# TITLE 21—FOOD AND DRUGS


| Chap. | | Sec. |
|---|---|---|
| **1.** | **Adulterated or Misbranded Foods or Drugs** | **1** |
| **2.** | **Teas** | **41** |
| **3.** | **Filled Milk** | **61** |
| **4.** | **Animals, Meats, and Meat and Dairy Products** | **71** |
| **5.** | **Viruses, Serums, Toxins, Antitoxins, and Analogous Products** | **151** |
| **5A.** | **Bureau of Narcotics [Omitted]** | **161** |
| **6.** | **Narcotic Drugs [Repealed or Transferred]** | **171** |
| **7.** | **Practice of Pharmacy and Sale of Poisons in Consular Districts in China** | **201** |
| **8.** | **Narcotic Farms [Repealed]** | **221** |
| **9.** | **Federal Food, Drug, and Cosmetic Act** | **301** |
| **10.** | **Poultry and Poultry Products Inspection** | **451** |
| **11.** | **Manufacture of Narcotic Drugs [Repealed]** | **501** |
| **12.** | **Meat Inspection** | **601** |
| **13.** | **Drug Abuse Prevention and Control** | **801** |
| **14.** | **Alcohol and Drug Abuse Educational Programs and Activities [Repealed]** | **1001** |
| **15.** | **Egg Products Inspection** | **1031** |
| **16.** | **Drug Abuse Prevention, Treatment, and Rehabilitation** | **1101** |
| **17.** | **National Drug Enforcement Policy [Repealed]** | **1201** |
| **18.** | **President's Media Commission on Alcohol and Drug Abuse Prevention** | **1301** |
| **19.** | **Pesticide Monitoring Improvements** | **1401** |
| **20.** | **National Drug Control Program** | **1501** |


CROSS REFERENCES

Biological products, regulation, see section 262 of Title 42, The Public Health and Welfare.

Narcotics, instruction as to nature and effect of, see section 111 et seq. of Title 20, Education.

Packers and Stockyards Act, see section 181 et seq. of Title 7, Agriculture.

TITLE REFERRED TO IN OTHER SECTIONS

This title is referred to in title 18 section 3050.

## CHAPTER 1—ADULTERATED OR MISBRANDED FOODS OR DRUGS

SUBCHAPTER I—FEDERAL FOOD AND DRUGS ACT OF 1906


Sec.

1 to 15. Repealed or Transferred.

Sec.

SUBCHAPTER II—MISCELLANEOUS PROVISIONS

16. Introduction into, or sale in, State or Territory or District of Columbia of dairy or food products falsely labeled or branded.
17. Penalty for sale or introduction of falsely labeled dairy or food products; venue.
18. Suspension of importation of adulterated articles.
19. Repealed.
20. Apples in interstate commerce; standard grades.
21. Branding grades on barrels of apples.
22. Barrels misbranded.
23. Penalties.
24. Omitted.
25. Oleomargarine, butterine, or imitation butter or cheese transported into a State subject to its police powers.
26. Omitted.


SUBCHAPTER I—FEDERAL FOOD AND DRUGS ACT OF 1906

### §§ 1 to 5. Repealed. June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059

Section 1, act June 30, 1906, ch. 3915, §1, 34 Stat. 768, made it unlawful to manufacture adulterated or misbranded foods or drugs in Territories or District of Columbia and provided penalty for violations. See sections 331 and 333 of this title.

Section 2, act June 30, 1906, ch. 3915, §2, 34 Stat. 768, prohibited introduction, shipment, delivery or sale of adulterated or misbranded foods or drugs in interstate or foreign commerce, provided penalty for violations and exempted exports conforming to specifications of foreign purchaser and not in conflict with laws of foreign country importing the same. See sections 331, 333 and 381 of this title.

Section 3, acts June 30, 1906, ch. 3915, §3, 34 Stat. 768; Mar. 4, 1913, ch. 141, §1, 37 Stat. 736, authorized Secretaries of the Treasury, Agriculture, and Commerce to make uniform rules and regulations for enforcement of food and drug laws, including collection and examination of specimens. See section 371 of this title.

Section 4, act June 30, 1906, ch. 3915, §12, 34 Stat. 772, provided that act or omission of officer, agent, and so forth, of corporation, shall be deemed act or omission of corporation.

Section 5, act June 30, 1906, ch. 3915, §12, 34 Stat. 772, defined ''territory'' and ''person''. See section 321 of this title and section 1 of Title 1, General Provisions.

EFFECTIVE DATE OF REPEAL

Section 902(a) of act June 25, 1938, ch. 675, 52 Stat. 1059, which repealed sections 1 to 5, 7 to 14, and 15 of this title, provided that the repeal of those sections should take effect upon the effective date of act June 25, 1938, which was to take effect twelve months after the date of its enactment. Act June 23, 1939, ch. 242, §2(b), 53 Stat. 854, provided that: ''The provisions of such act of June 30, 1906, as amended, to the extent that they impose, or authorize the imposition of, any re-

quirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act [section 343(k) of this title], shall remain in force until January 1, 1940.''

### § 6. Transferred

CODIFICATION

Section, act Mar. 4, 1923, ch. 268, 42 Stat. 1500, was transferred to section 321a of this title.

### §§ 7 to 14. Repealed. June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059

Section 7, act June 30, 1906, ch. 3915, § 6, 34 Stat. 769, defined ''drug'' and ''food''. See section 321 of this title.

Section 8, act June 30, 1906, ch. 3915, § 7, 34 Stat. 769, deemed drugs to be adulterated when sold having a difference from recognized standards, except where there is an explanatory statement on or in container, and when sold below professed standard; confectioneries, when containing mineral substances, poisonous color or flavors, other deleterious ingredients, liquors or narcotics; food, when concerned with injurious mixtures, use of substitutes, abstraction of valuable constituents, concealment of damage or inferiority, deleterious ingredients, preservatives in shipment conditionally excepted, animal or vegetable substances unfit for food and products of animals diseased or having died otherwise than by slaughter. See sections 342 and 351 of this title.

Section 9, act June 30, 1906, ch. 3915, § 8, 34 Stat. 771, defined ''misbranded'' and provided for its application to drugs and food. See sections 343 and 352 of this title.

Section 10, acts June 30, 1906, ch. 3915, § 8, 34 Stat. 771; Aug. 23, 1912, ch. 352, 37 Stat. 416; Mar. 3, 1913, ch. 117, 37 Stat. 732; July 24, 1919, ch. 26, 41 Stat. 271; July 8, 1930, ch. 874, 46 Stat. 1019, deemed drugs to be misbranded when there is an imitation or use of name of other article, when there is removal and substitution of contents of package or failure to state on label quantity or proportion of narcotics therein, and when there is a false statement of curative or therapeutic effect; and food, when there is an imitation or use of name of other article, when there is a false label or brand removal and substitution of contents of package, or failure to state or label quantity or proportion of narcotics therein, when the packages are not marked with weight, with certain variations and exemptions permitted, when there are false or misleading statements on package or label as to ingredients or substances; and food, when mixtures or compounds under distinctive names, the articles are labeled, branded as compounds, imitations, or blends; construed the term ''blend'' and related to disclosure of trade formulas of proprietary foods, and canned food. See sections 321b, 341, 343 and 352 of this title.

Section 11, acts June 30, 1906, ch. 3915, § 4, 34 Stat. 769; Jan. 18, 1927, ch. 39, 44 Stat. 1003, provided for examination of specimens, notice of adulteration or misbranding, hearing, certification of violations to United States district attorney and notice of judgment.

Section 12, act June 30, 1906, ch. 3915, § 5, 34 Stat. 769, provided for prosecution by district attorneys for enforcement of penalties.

Section 13, act June 30, 1906, ch. 3915, § 9, 34 Stat. 771, provided for a seller's guaranty as protection to dealer. See section 333 of this title.

Section 14, act June 30, 1906, ch. 3915, § 10, 34 Stat. 771, provided for seizure of articles by libel for condemnation, at suit of and in name of United States, in United States district court where found, conforming to proceedings in admiralty, with right to trial by jury, destruction or sale of adulterated or misbranded articles, bond and payment of proceeds into Treasury of United States. See sections 332, 334 and 337 of this title.

EFFECTIVE DATE OF REPEAL

For effective date of repeal, see section 902(a) of act June 25, 1938, set out as a note under sections 1 to 5 of this title.

### § 14a. Transferred

CODIFICATION

Section, act June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204, and amended, which related to examination of sea food on request of packer, marking of food with results, fees, and penalties, was successively renumbered section 702A and then 706 of the Federal Food, Drug, and Cosmetic Act by act July 12, 1943, ch. 221, title II, § 201, 57 Stat. 500, and by Pub. L. 102–571, title I, § 106(3), Oct. 29, 1992, 106 Stat. 4498, and was successively classified to section 372a and then 376 of this title.

### § 15. Repealed. June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059

Section, act June 30, 1906, ch. 3915, § 11, 34 Stat. 772, provided for examination of samples of imports, refusal of admission and delivery to consignee, delivery to consignee pending examination and decision on bond and charges for storage and lien therefor. See section 381 of this title.

EFFECTIVE DATE OF REPEAL

For effective date of repeal, see section 902(a) of act June 25, 1938, set out as a note under sections 1 to 5 of this title.

## SUBCHAPTER II—MISCELLANEOUS PROVISIONS

### § 16. Introduction into, or sale in, State or Territory or District of Columbia of dairy or food products falsely labeled or branded

No person or persons, company or corporation, shall introduce into any State or Territory of the United States or the District of Columbia from any other State or Territory of the United States or the District of Columbia, or sell in the District of Columbia or in any Territory any dairy or food products which shall be falsely labeled or branded as to the State or Territory in which they are made, produced, or grown, or cause or procure the same to be done by others.

(July 1, 1902, ch. 1357, § 1, 32 Stat. 632.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 17 of this title.

### § 17. Penalty for sale or introduction of falsely labeled dairy or food products; venue

If any person or persons violate the provisions of section 16 of this title, either in person or through another, he shall be guilty of a misdemeanor and shall be punished by a fine of not less than $500 nor more than $2,000. The jurisdiction for the prosecution of said misdemeanor shall be within the district of the United States court in which it is committed.

(July 1, 1902, ch. 1357, § 2, 32 Stat. 632.)

FEDERAL RULES OF CRIMINAL PROCEDURE

Special venue provisions of section as not affected by rule 18, see Notes of Advisory Committee on Rules set out under rule 18, Title 18, Appendix, Crimes and Criminal Procedure.

### § 18. Suspension of importation of adulterated articles

Whenever the President is satisfied that there is good reason to believe that any importation is being made, or is about to be made, into the

United States, from any foreign country, of any article used for human food or drink that is adulterated to an extent dangerous to the health or welfare of the people of the United States, or any of them, he may issue his proclamation suspending the importation of such articles from such country for such period of time as he may think necessary to prevent such importation; and during such period it shall be unlawful to import into the United States from the countries designated in the proclamation of the President any of the articles the importation of which is so suspended.

(Aug. 30, 1890, ch. 839, § 4, 26 Stat. 415.)

### § 19. Repealed. May 29, 1928, ch. 901, § 1(100), 45 Stat. 993

Section, act May 23, 1908, ch. 192, 35 Stat. 261, related to report to the Congress of expenditures in enforcing food and drug laws.

### § 20. Apples in interstate commerce; standard grades

The standard grades for apples when packed in barrels which shall be shipped or delivered for shipment in interstate or foreign commerce, or which shall be sold or offered for sale within the District of Columbia or the Territories of the United States shall be as follows: Apples of one variety, which are well-grown specimens, hand picked, of good color for the variety, normal shape, practically free from insect and fungous injury, bruises, and other defects, except such as are necessarily caused in the operation of packing, or apples of one variety which are not more than 10 per centum below the foregoing specifications shall be ''Standard grade minimum size two and one-half inches'', if the minimum size of the apples is two and one-half inches in transverse diameter; ''Standard grade minimum size two and one-fourth inches'', if the minimum size of the apples is two and one-fourth inches in transverse diameter; or ''Standard grade minimum size two inches'', if the minimum size of the apples is two inches in transverse diameter.

(Aug. 3, 1912, ch. 273, § 2, 37 Stat. 250.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 21, 22, 23 of this title.

### § 21. Branding grades on barrels of apples

The barrels in which apples are packed in accordance with the provisions of sections 20 to 23 of this title may be branded in accordance with the provisions of section 20 of this title.

(Aug. 3, 1912, ch. 273, § 3, 37 Stat. 251.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 22, 23 of this title.

### § 22. Barrels misbranded

Barrels packed with apples shall be deemed to be misbranded within the meaning of sections 20 to 23 of this title—

First. If the barrel bears any statement, design, or device indicating that the apples contained therein are ''Standard'' grade and the apples when packed do not conform to the requirements prescribed by section 20 of this title.

Second. If the barrel bears any statement, design, or device indicating that the apples contained therein are ''Standard'' grade and the barrel fails to bear also a statement of the name of the variety, the name of the locality where grown, and the name of the packer or the person by whose authority the apples were packed and the barrel marked.

(Aug. 3, 1912, ch. 273, § 5, 37 Stat. 251.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 21, 23 of this title.

### § 23. Penalties

Any person, firm or corporation, or association who shall knowingly pack or cause to be packed apples in barrels or who shall knowingly sell or offer for sale such barrels in violation of the provisions of sections 20 to 23 of this title shall be liable to a penalty of $1 and costs for each such barrel so sold or offered for sale, to be recovered at the suit of the United States in any court of the United States having jurisdiction.

(Aug. 3, 1912, ch. 273, § 6, 37 Stat. 251.)

CODIFICATION

Section is also set out as section 233 of Title 15, Commerce and Trade.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 21, 22 of this title.

### § 24. Omitted

CODIFICATION

Section, act Mar. 4, 1915, ch. 144, 38 Stat. 1102, related to payment of the cost of inspection under a provision authorizing the investigation of the character of chemical and physical tests applied to American food products in foreign countries and the inspection of such products before shipment to such countries at the request of the shippers or owners. That provision was repeated in subsequent appropriation acts but was omitted from the appropriation act of July 12, 1943, ch. 221, 57 Stat. 494, and from all subsequent appropriation acts.

### § 25. Oleomargarine, butterine, or imitation butter or cheese transported into a State subject to its police powers

All articles known as oleomargarine, butterine, imitation, process, renovated, or adulterated butter, or imitation cheese, or any substance in the semblance of butter or cheese not the usual product of the dairy and not made exclusively of pure and unadulterated milk or cream, transported into any State or Territory or the District of Columbia, and remaining therein for use, consumption, sale, or storage therein, shall, upon the arrival within the limits of such State or Territory or the District of Columbia, be subject to the operation and effect of the laws of such State or Territory or the District of Columbia, enacted in the exercise of its police powers to the same extent and in the same manner as though such articles or substances had been produced in such State or Territory or the District of Columbia, and shall not

be exempt therefrom by reason of being introduced therein in original packages or otherwise.

(May 9, 1902, ch. 784, § 1, 32 Stat. 193.)

CROSS REFERENCES

Colored oleomargarine, intrastate sales of, see section 347 et seq. of this title.

### § 26. Omitted

CODIFICATION

Section, which was from the appropriation acts of Jan. 18, 1927, ch. 39, 44 Stat. 984; May 16, 1928, ch. 572, 45 Stat. 548; Feb. 16, 1929, ch. 227, 45 Stat. 1198; May 27, 1930, ch. 341, 46 Stat. 424, and subsequent Department of Agriculture Appropriation Acts to and including act June 28, 1944, ch. 296, § 4, 58 Stat. 461, and related to inspection of food and other products, is covered by section 2256 of Title 7, Agriculture.

## CHAPTER 2—TEAS

Sec.
41. Importation of tea inferior to standard.
42. Board of experts; appointment; term; vacancies; compensation.
43. Standards of purity; duplicate samples at customhouses and for importers and dealers.
44. Bonds of importers; examination; importations at ports having no examiner.
45. Permit for delivery; retention of inferior grades; reexamination; partial delivery.
46. Examiners; examination according to usages of trade.
46a. Deposit of fee before examination of tea.
47. United States Board of Tea Appeals; permit for delivery; exportation or destruction of inferior grades.
48. Reexamination; findings by examiner; assistance of experts.
49. Reimporting rejected teas; forfeiture.
50. Regulations.

### § 41. Importation of tea inferior to standard

It shall be unlawful for any person or persons or corporation to import or bring into the United States any merchandise as tea which is inferior in purity, quality, and fitness for consumption to the standards provided in section 43 of this title, and the importation of all such merchandise is prohibited, except as provided in the Harmonized Tariff Schedule of the United States.

(Mar. 2, 1897, ch. 358, § 1, 29 Stat. 604; May 16, 1908, ch. 170, 35 Stat. 163; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; May 24, 1962, Pub. L. 87–456, title III, § 303(a), 76 Stat. 77; Aug. 23, 1988, Pub. L. 100–418, title I, § 1214(*l*), 102 Stat. 1158.)

REFERENCES IN TEXT

The Harmonized Tariff Schedule of the United States, referred to in text, is not set out in the Code. See Publication of Harmonized Tariff Schedule note set out under section 1202 of Title 19, Customs Duties.

AMENDMENTS

1988—Pub. L. 100–418 substituted ''Harmonized Tariff Schedule of the United States'' for ''Tariff Schedules of the United States''.

1962—Pub. L. 87–456 inserted ''except as provided in the Tariff Schedules of the United States'' at end of first sentence, and struck out second sentence which related to the importation under bond of tea inferior to standards, tea waste, tea siftings, or tea sweepings, under regulations prescribed by the Secretary of the Treasury, for the sole purpose of manufacturing theine, caffeine, or other chemical products whereby the identity and character of the original material is entirely destroyed or changed and that the bonds shall be subject to the approval only of the collector of customs at the port of entry.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–418 effective Jan. 1, 1989, and applicable with respect to articles entered on or after such date, see section 1217(b)(1) of Pub. L. 100–418, set out as an Effective Date note under section 3001 of Title 19, Customs Duties.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–456 effective with respect to articles entered, or withdrawn from warehouse, for consumption on or after Aug. 31, 1963, see section 501(a) of Pub. L. 87–456.

SHORT TITLE

Act July 12, 1943, ch. 221, title II, 57 Stat. 499, provided in part that act Mar. 2, 1897, which is classified generally to this chapter, may be cited as the ''Tea Importation Act''.

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out in the Appendix to Title 5, Government Organization and Employees. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Food and Drug Administration in Department of Agriculture and its functions, except those functions relating to administration of Insecticide Act of 1910 and Naval Stores Act, transferred to Federal Security Agency, to be administered under direction and supervision of Federal Security Administrator, by Reorg. Plan No. IV of 1940, set out in the Appendix to Title 5.

The powers and duties of Secretary of the Treasury under this section were conferred upon Secretary of Agriculture by act May 31, 1920.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 43, 45 of this title.

### § 42. Board of experts; appointment; term; vacancies; compensation

On or before February 15 of each year, the Secretary of Health and Human Services shall appoint a board, to consist of seven members, each of whom shall be an expert in teas, and who shall prepare and submit to him standard samples of tea. The persons so appointed shall be at all times subject to removal by the said Secretary, and shall serve for the term of one year. Vacancies in the said board occurring by removal, death, resignation, or any other cause shall be forthwith filled by the Secretary of Health and Human Services by appointment, such appointee to hold for the unexpired term. Said board shall appoint a presiding officer, who shall be the medium of all communications to or

from such board. Each member of said board shall receive as compensation the sum of $50 per annum, which, together with all necessary expenses while engaged upon the duty herein provided, shall be paid by the Secretary.

(Mar. 2, 1897, ch. 358, §2, 29 Stat. 605; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, §12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; July 12, 1943, ch. 221, title II, 57 Stat. 500; 1953 Reorg. Plan No. 1, §5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695.)

AMENDMENTS

1943—Act July 12, 1943, provided that the Administrator should pay the salaries and expenses of the board members.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 43, 45 of this title.

## §43. Standards of purity; duplicate samples at customhouses and for importers and dealers

The Secretary of Health and Human Services, upon the recommendation of the board of experts provided in section 42 of this title, shall fix and establish uniform standards of purity, quality, and fitness for consumption of all kinds of teas imported into the United States, and shall procure and deposit in the customhouses of the ports of New York, Chicago, San Francisco, and such other ports as he may determine, duplicate samples of such standards. Said Secretary shall procure a sufficient number of other duplicate samples of such standards to supply the importers and dealers in tea at all ports desiring the same at cost. All teas, or merchandise described as tea, of inferior purity, quality, and fitness for consumption to such standards shall be deemed within the prohibition of section 41 of this title.

(Mar. 2, 1897, ch. 358, §3, 29 Stat. 605; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, §12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, §5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695.)

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 41, 45 of this title.

## §44. Bonds of importers; examination; importations at ports having no examiner

On making entry at the customhouse of all teas, or merchandise described as tea, imported into the United States, the importer or consignee shall give a bond to the collector of the port that such merchandise shall not be removed from the warehouse until released by the collector, after it shall have been duly examined with reference to its purity, quality, and fitness for consumption. For the purpose of such examination samples of each line in every invoice of tea shall be submitted by the importer or consignee to the examiner, together with the sworn statement of such importer or consignee that such samples represent the true quality of each and every part of the invoice and accord with the specifications therein contained; or in the discretion of the Secretary of Health and Human Services, such samples shall be obtained by the examiner and compared by him with the standards established by this chapter. In cases where said tea, or merchandise described as tea, is entered at ports where there is no qualified examiner as provided in section 46 of this title, the consignee or importer shall in the manner aforesaid furnish under oath a sample of each line of tea to the collector or other revenue officer to whom is committed the collection of duties, and said officer shall also draw or cause to be drawn samples of each line in every invoice and shall forward the same to a duly qualified examiner as provided in said section. The bond required by this section shall also be conditioned for the payment of all customhouse charges which may attach to such merchandise prior to its being released or destroyed (as the case may be) under the provisions of this chapter.

(Mar. 2, 1897, ch. 358, §4, 29 Stat. 605; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, §12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, §5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695.)

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

All offices of collector of customs in Bureau of Customs of Department of the Treasury ordered abolished, with such offices to be terminated not later than Dec. 31, 1966, by Reorg. Plan No. 1 of 1965, eff. May 25, 1965, 30 F.R. 7035, 79 Stat. 1317, set out in the Appendix to

Title 5, Government Organization and Employees. All functions of offices eliminated were already vested in Secretary of the Treasury by Reorg. Plan No. 26 of 1950, eff. July 31, 1950, 15 F.R. 4935, 64 Stat. 1280, also set out in the Appendix to Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 45, 46 of this title.

### § 45. Permit for delivery; retention of inferior grades; reexamination; partial delivery

If, after an examination as provided in section 44 of this title, the tea is found by the examiner to be equal in purity, quality, and fitness for consumption to the standards provided in sections 41 to 44 of this title, and no reexamination shall be demanded by the collector as provided in section 47 of this title, a permit shall at once be granted to the importer or consignee declaring the tea free from the control of the customs authorities; but if on examination such tea, or merchandise described as tea, is found, in the opinion of the examiner, to be inferior in purity, quality, and fitness for consumption to the said standards the importer or consignee shall be immediately notified, and the tea, or merchandise described as tea, shall not be released by the customhouse, unless on a reexamination called for by the importer or consignee the finding of the examiner shall be found to be erroneous. Should a portion of the invoice be passed by the examiner, a permit shall be granted for that portion and the remainder held for further examination, as provided in said section 47.

(Mar. 2, 1897, ch. 358, § 5, 29 Stat. 605.)

TRANSFER OF FUNCTIONS

For abolition of the offices of collector of customs, see note set out under section 44 of this title.

### § 46. Examiners; examination according to usages of trade

The examination provided for by this chapter shall be made by a duly qualified examiner at a port where standard samples are established, and where the merchandise is entered at ports where there is no qualified examiner, the examination shall be made at that one of said ports which is nearest the port of entry, and that for this purpose samples of the merchandise, obtained in the manner prescribed by section 44 of this title, shall be forwarded to the proper port by the collector or chief officer at the port of entry. In all cases of examination or reexamination of teas, or merchandise described as tea, by examiners or the United States Board of Tea Appeals under the provisions of this chapter, the purity, quality, and fitness for consumption of the same shall be tested according to the usages and customs of the tea trade, including the testing of an infusion of the same in boiling water and, if necessary, chemical analysis.

(Mar. 2, 1897, ch. 358, § 7, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712, 713.)

TRANSFER OF FUNCTIONS

For abolition of the offices of collector of customs, see note set out under section 44 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 44 of this title.

### § 46a. Deposit of fee before examination of tea

No tea or merchandise described as tea shall be examined for importation into the United States, or released by the Customs Service, under this chapter unless the importer or consignee of such tea or merchandise has paid, before the examination, a fee in an amount equal to—

(1) 10 cents for each hundred weight or fraction thereof of the tea or merchandise; or

(2) the approximate cost of the examinations;

whichever amount is less. Such fee shall be deposited into the Treasury of the United States as miscellaneous receipts.

(Mar. 2, 1897, ch. 358, § 13, formerly act July 1, 1941, ch. 269, title II, 55 Stat. 478; renumbered § 13 of act Mar. 2, 1897, and amended Aug. 10, 1993, Pub. L. 103–66, title IV, § 4401, 107 Stat. 378.)

PRIOR PROVISIONS

Provisions similar to those comprising this section were contained in the following appropriation act: June 27, 1940, ch. 437, title I, 54 Stat. 632.

AMENDMENTS

1993—Pub. L. 103–66, § 4401(2), amended section generally. Prior to amendment, section read as follows: ''On and after July 1, 1940, no tea, or merchandise described as tea, shall be examined for importation into the United States, or released by the Collector, under this chapter unless the importer or consignee of such tea or merchandise, prior to such examination, has paid for deposit into the Treasury of the United States as miscellaneous receipts, a fee of 3.5 cents for each hundred weight or fraction thereof of such tea and merchandise.''

### § 47. United States Board of Tea Appeals; permit for delivery; exportation or destruction of inferior grades

In case the collector, importer, or consignee shall protest against the finding of the examiner, the matter in dispute shall be referred for decision to the United States Board of Tea Appeals, to consist of three employees of the Department of Health and Human Services, to be designated by the Secretary of Health and Human Services. If such board shall, after due examination, find the tea in question to be equal in purity, quality, and fitness for consumption to the proper standards, a permit shall be issued by the collector for its release and delivery to the importer; but if upon such final reexamination by such board the tea shall be found to be inferior in purity, quality, and fitness for consumption to the said standards, the importer or consignee shall give a bond, with security satisfactory to the collector, to export said tea, or merchandise described as tea, out of the limits of the United States within a period of six months after such final reexamination; and if the same shall not have been exported within the time specified, the collector, at the expiration of that time, shall cause the same to be destroyed.

(Mar. 2, 1897, ch. 358, § 6, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712, 713; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953,

18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

CHANGE OF NAME

''Department of Health and Human Services'' substituted in text for ''Department of Health, Education, and Welfare'' and ''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see note set out under section 41 of this title.

For abolition of the offices of the collector of customs, see note set out under section 44 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 45 of this title.

### § 48. Reexamination; findings by examiner; assistance of experts

In cases of reexamination of teas, or merchandise described as teas, by the United States Board of Tea Appeals in pursuance of the provisions of this chapter, samples of the tea, or merchandise described as tea, in dispute, for transmission to such board for its decision, shall be put up and sealed by the examiner in the presence of the importer or consignee if he so desires, and transmitted to such board, together with a copy of the finding of the examiner, setting forth the cause of condemnation and the claim or ground of the protest of the importer relating to the same, such samples, and the papers therewith, to be distinguished by such mark that the same may be identified. The decision of such board shall be in writing, signed by them, and transmitted, together with the record and samples, within three days after the rendition thereof, to the collector, who shall forthwith furnish the examiner and the importer or consignee with a copy of said decision or finding. The United States Board of Tea Appeals shall be authorized to obtain the advice, when necessary, of persons skilled in the examination of teas, who shall each receive for his services in any particular case a compensation not exceeding $5.

(Mar. 2, 1897, ch. 358, § 8, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712.)

TRANSFER OF FUNCTIONS

For abolition of the offices of the collector of customs, see note set out under section 44 of this title.

### § 49. Reimporting rejected teas; forfeiture

No imported teas which have been rejected by a customs examiner or by the United States Board of Tea Appeals, and exported under the provisions of this chapter, shall be reimported into the United States under the penalty of forfeiture for a violation of this prohibition.

(Mar. 2, 1897, ch. 358, § 9, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712.)

### § 50. Regulations

The Secretary of Health and Human Services shall have the power to enforce the provisions of this chapter by appropriate regulations.

(Mar. 2, 1897, ch. 358, § 10, 29 Stat. 607; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see note set out under section 41 of this title.

## CHAPTER 3—FILLED MILK

Sec.
61. Definitions.
62. Manufacture, shipment, or delivery for shipment in interstate or foreign commerce prohibited.
63. Penalties; acts of agents deemed acts of principals.
64. Regulations for enforcement.

FEDERAL FOOD, DRUG, AND COSMETIC ACT

By virtue of act June 25, 1938, ch. 675, § 902(c), 52 Stat. 1059 [section 392(b) of this title], nothing contained in section 301 et seq. of this title shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of sections 61 to 64 of this title.

BUREAU OF DAIRY INDUSTRY

General provisions, see sections 401 to 404 of Title 7, Agriculture.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 392 of this title.

### § 61. Definitions

Whenever used in this chapter—

(a) The term ''person'' includes an individual, partnership, corporation, or association;

(b) The term ''interstate or foreign commerce'' means commerce (1) between any State, Territory, or possession, or the District of Columbia, and any place outside thereof; (2) between points within the same State, Territory, or possession, or within the District of Columbia, but through any place outside thereof; or (3) within any Territory or possession, or within the District of Columbia; and

(c) The term ''filled milk'' means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated. This definition shall not in-

clude any distinctive proprietary food compound not readily mistaken in taste for milk or cream or for evaporated, condensed, or powdered milk, or cream where such compound (1) is prepared and designed for feeding infants and young children and customarily used on the order of a physician; (2) is packed in individual cans containing not more than sixteen and one-half ounces and bearing a label in bold type that the content is to be used only for said purpose; (3) is shipped in interstate or foreign commerce exclusively to physicians, wholesale and retail druggists, orphan asylums, child-welfare associations, hospitals, and similar institutions and generally disposed of by them.

(Mar. 4, 1923, ch. 262, § 1, 42 Stat. 1486.)

SHORT TITLE

Act July 12, 1943, ch. 221, title II, 57 Stat. 499, provided in part that act Mar. 4, 1923, which enacted this chapter, may be cited as the ''Filled Milk Act''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 62 of this title.

### § 62. Manufacture, shipment, or delivery for shipment in interstate or foreign commerce prohibited

It is declared that filled milk, as defined in section 61 of this title, is an adulterated article of food, injurious to the public health, and its sale constitutes a fraud upon the public. It shall be unlawful for any person to manufacture within any Territory or possession, or within the District of Columbia, or to ship or deliver for shipment in interstate or foreign commerce, any filled milk.

(Mar. 4, 1923, ch. 262, § 2, 42 Stat. 1487.)

### § 63. Penalties; acts of agents deemed acts of principals

Any person violating any provision of this chapter shall upon conviction thereof be subject to a fine of not more than $1,000 or imprisonment of not more than one year, or both. When construing and enforcing the provisions of this chapter, the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association, within the scope of his employment or office, shall in every case be deemed the act, omission, or failure, of such individual, partnership, corporation, or association, as well as of such person.

(Mar. 4, 1923, ch. 262, § 3, 42 Stat. 1487.)

CODIFICATION

The original text of this section contained a further provision that no penalty should be enforced for any violation occurring within 30 days after act Mar. 4, 1923 became law and was omitted as temporary and obsolete.

### § 64. Regulations for enforcement

The Secretary of Health and Human Services is authorized and directed to make and enforce such regulations as may in his judgment be necessary to carry out the purposes of this chapter.

(Mar. 4, 1923, ch. 262, § 4, as added Aug. 27, 1935, ch. 743, 49 Stat. 885; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see note set out under section 41 of this title.

## CHAPTER 4—ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS

SUBCHAPTER I—EXAMINATION OF ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS

Sec.
71 to 99. Transferred, Repealed, or Omitted.

SUBCHAPTER II—IMPORTATION OF CATTLE AND QUARANTINE

101. Suspension of importation of all animals.
102. Quarantine of imported animals.
103. Importation, except at quarantine ports, prohibited; slaughter of infected animals; appraisal; payment.
104. Importation of animals.
(a) In general.
(b) Penalties.
105. Inspection of animals.
106, 107. Omitted.

SUBCHAPTER III—PREVENTION OF INTRODUCTION AND SPREAD OF CONTAGION

111. Regulations to prevent contagious diseases.
112. Investigations as to pleuropneumonia, and other diseases; regulations.
112a. Omitted.
113. Measures to prevent exportation of diseased livestock and live poultry.
113a. Establishment of research laboratories for foot-and-mouth disease and other animal diseases; research contracts; employment of technicians and scientists; appropriations.
114. Regulations for suppression of diseases; cooperation of States and Territories.
114a. Control and eradication of diseases; cooperation of States and farmers' associations; purchase and destruction of diseased animals; ''State'' defined.
114a–1. Interstate movement of domestic animals reacting to tests for brucellosis; immediate slaughter; rules and regulations.
114b. Cooperation in animal disease control.
114c. Use of funds.
114d. Sale of sterile screwworms.
(a) In general.
(b) Terms of sale.
(c) Deposit of proceeds.
114d–1. Cooperation with public and private entities.
114d–2 to 114d–6. Repealed.
114e. Control and eradication of cattle grubs; research and investigations.
114f. ''State'' defined; authorization of appropriations.
114g. Hog cholera eradication program.
114h. Advisory committee.
(a) Establishment; membership.
(b) Functions.
(c) Employment status; expenses.

Sec.
114i. Pseudorabies eradication.
(a) Findings.
(b) Establishment of program.
(c) Use of funds for testing and control of pseudorabies.
(d) Authorization of appropriations.
115. Transportation of diseased livestock and live poultry prohibited.
116. Shipment of certain cattle excepted.
117. Penalties for transportation of diseased livestock or live poultry.
(a) Criminal penalty.
(b) Civil penalty.
118. Duty of United States attorneys.
119. Agents to examine and report on methods of treatment of animals, and means for suppression of diseases.
120. Regulation of exportation and transportation of infected livestock and live poultry.
121. Shipments from areas suspected infected; control of animals and live poultry.
122. Offenses; penalty.
123. Quarantine.
124. Transportation or delivery therefor from quarantined State or Territory or portion thereof, of quarantined animals and live poultry, forbidden.
125. Regulations for inspection, disinfection, and certification, and delivery and shipment of quarantined animals and live poultry from State or Territory.
126. Moving quarantined animals and live poultry from State or Territory, under regulations.
127. Transportation from quarantined State, Territory, etc.; penalty.
128. Extension of quarantine law to carriers in interstate commerce.
129. Expenses for arrest and eradication of contagious or infectious diseases or pests of animals, poultry, or plants.
130. Pleuropneumonia in District of Columbia; duties of Council of the District of Columbia.
131. Fences along international boundary lines to keep out diseased animals.
132, 133. Transferred or Repealed.
134. Definitions.
134a. Seizure, quarantine, and disposal of livestock or poultry to guard against introduction or dissemination of communicable disease.
(a) Authority of Secretary.
(b) Determination of extraordinary emergency due to dangerous communicable disease; seizure, quarantine, and disposal of animals; action authorized only if adequate measures not taken by State or other jurisdiction; notice to State or other jurisdiction.
(c) Notice to owner to quarantine or to dispose of animal, carcass, product, or article; action on failure to comply; costs.
(d) Compensation of owner; fair market value; payments from State or other source; availability of funds.
(e) Restriction on payment of compensation in cases of violation of law or regulation.
134b. Regulations for clean and sanitary movement of animals.
134c. Regulations for movement of animals affected or exposed to communicable disease.
134d. Inspections and seizures; issuance of warrants.
134e. Enforcement provisions.
(a) Criminal and civil penalties.
(b) Injunctive proceedings.
134f. Promulgation of regulations.
134g. Authority in addition to other laws; repeal of inconsistent provisions.
Sec.
134h. Separability.
135. International animal quarantine station; establishment; acceptance of gifts; cooperation with breeders' organizations; collection of fees.
135a. Smuggling penalties.
(a) Criminal penalty.
(b) Civil penalty.
135b. Authorization of appropriations.
136. Additional inspection services.
136a. Collection of fees for inspection services.
(a) Quarantine, inspection and transportation fees.
(b) Omitted.
(c) Animal inspection and veterinary diagnostics.
(d) Regulations.
(e) Recovery of amounts owed.
(f) Definitions.

SUBCHAPTER IV—IMPORTATION OF MILK AND CREAM

141. Prohibition of importation without permit.
142. Milk or cream when unfit for importation.
143. Inspection; certified statement in lieu thereof; waiver of requirements of section 142; regulations; suspension and revocation of permits.
144. Unlawful receiving of imported milk or cream.
145. Penalties.
146. Authorization of appropriations.
147. Repeal of inconsistent laws.
148. Powers of State with respect to milk or cream lawfully imported.
149. Definitions.

## SUBCHAPTER I—EXAMINATION OF ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS

### §§ 71 to 92. Transferred

CODIFICATION

Section 71, act Mar. 4, 1907, ch. 2907, 34 Stat. 1260, which related to inspection of meat and meat food products, examination of cattle before slaughtering, separate slaughtering of diseased animals and examination of carcasses, was transferred to section 603 of this title.

Section 72, act Mar. 4, 1907, ch. 2907, 34 Stat. 1260, which related to post mortem examination of carcasses, marking and labeling, destruction of condemned carcasses, and reinspection, was transferred to section 604 of this title.

Section 73, act Mar. 4, 1907, ch. 2907, 34 Stat. 1261, which related to examination of carcasses brought into slaughtering or packing establishments and of meat food products issued from and returned thereto, was transferred to section 605 of this title.

Section 74, act Mar. 4, 1907, ch. 2907, 34 Stat. 1261, which related to examination and inspection of meat food products, marks of inspection, destruction of condemned products, and products for export, was transferred to section 606 of this title.

Section 75, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to labeling of receptacles and coverings of meat and meat food products inspected and passed, supervision by inspectors, prohibition of sales under false names, was transferred to section 607 of this title.

Section 76, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to sanitary inspection and regulation of slaughtering and packing establishments, and rejection of meat or meat food products unfit for food, was transferred to section 608 of this title.

Section 77, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to examination of cattle and food products thereof slaughtered and prepared during night time, was transferred to section 609 of this title.

Section 78, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to prohibition of transportation of carcasses, meat, or meat food products not properly inspected and marked, was transferred to section 610 of this title.

Section 79, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to forgery, alteration, and unauthorized use of marks, labels, and certificates, was transferred to section 611 of this title.

Section 80, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to inspection of animals for export, was transferred to section 612 of this title.

Section 81, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to certificates of condition of animals for export, was transferred to section 613 of this title.

Section 82, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to clearance to vessels carrying cattle for export with proper certificate of inspection, was transferred to section 614 of this title.

Section 83, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to inspection of carcasses, the meat of which is intended for export, was transferred to section 615 of this title.

Section 84, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to certificates of condition of carcasses, the meat of which is intended for export, was transferred to section 616 of this title.

Section 85, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to clearance to vessels carrying meat for export with proper certificate of inspection, was transferred to section 617 of this title.

Section 86, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to official certificates of inspection and delivery of copies thereof to different parties, was transferred to section 618 of this title.

Section 87, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to prohibition of transportation or sale of meat or meat food products without complying with provisions of inspection law, was transferred to section 619 of this title.

Section 88, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to offenses and penalties, was transferred to section 620 of this title.

Section 89, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to appointment of inspectors, their duties, and rule making authority of the Secretary of Agriculture, was transferred to section 621 of this title.

Section 90, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to penalties for bribery, was transferred to section 622 of this title.

Section 91, acts Mar. 4, 1907, ch. 2907, 34 Stat. 1265; June 29, 1938, ch. 810, 52 Stat. 1235, which related to definitions, exceptions to inspection requirements in case of farmers and retailers, and penalties for sale of meat and meat food products unfit for food, was transferred to section 623 of this title.

Section 92, act Mar. 4, 1907, ch. 2907, 34 Stat. 1265, which was a proviso following the first sentence of section 91 of this title, was restored to that section and has been transferred to section 623 of this title.

### § 93. Repealed. May 29, 1928, ch. 901, § 1(92), 45 Stat. 993

Section, act Mar. 4, 1907, ch. 2907, 34 Stat. 1265, related to statement in annual estimates as to persons employed, their compensation and expenses.

### §§ 94 to 95. Transferred

CODIFICATION

Section 94, act June 30, 1914, ch. 131, 38 Stat. 420, which related to inspection of reindeer, was transferred to section 692 of this title.

Section 94a, act May 23, 1908, ch. 192, 35 Stat. 254, which related to inspection of dairy products for export, was transferred to section 693 of this title.

Section 95, acts June 30, 1906, ch. 3913, 34 Stat. 679; June 26, 1934, ch. 756, § 2, 48 Stat. 1225, which related to authorization of appropriations for expenses of inspection, was transferred to section 694 of this title.

### § 96. Repealed. Pub. L. 90–201, § 18, Dec. 15, 1967, 81 Stat. 600

Section, act July 24, 1919, ch. 26, 41 Stat. 241, provided for marking horse meat transported in interstate commerce. See section 619 of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective Dec. 15, 1967, see section 20 of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### §§ 97 to 97d. Omitted

CODIFICATION

Sections 97 to 97d, act July 30, 1947, ch. 356, title I, § 1, 61 Stat. 531, 532, set up a meat inspection fund and provided for payment for meat inspection service by the persons or organizations who were furnished such inspection on and after July 1, 1947. These provisions ceased to be effective on July 1, 1948, under section 98 of this title which requires the cost of such inspection to be borne by the United States. The unobligated balance in the meat inspection fund was carried to the general fund of the Treasury by act June 19, 1948, ch. 543, § 1, 62 Stat. 515.

### § 98. Transferred

CODIFICATION

Section, act June 5, 1948, ch. 423, 62 Stat. 344, which related to payment of cost of meat inspection, was transferred to section 695 of this title.

### § 99. Repealed. July 28, 1953, ch. 251, title I, § 101, 67 Stat. 208

Section, act Aug. 31, 1951, ch. 374, title I, § 101, 65 Stat. 229, related to reimbursement for excess expenses of meat inspection.

## SUBCHAPTER II—IMPORTATION OF CATTLE AND QUARANTINE

### § 101. Suspension of importation of all animals

Whenever, in the opinion of the President, it shall be necessary for the protection of animals in the United States against infectious or contagious diseases, he may, by proclamation, suspend the importation of all or any class of animals for a limited time, and may change, modify, revoke, or renew such proclamation, as the public good may require; and during the time of such suspension the importation of any such animals shall be unlawful.

(Aug. 30, 1890, ch. 839, § 9, 26 Stat. 416.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 104, 136a of this title; title 16 section 1540.

### § 102. Quarantine of imported animals

The Secretary of Agriculture is authorized, at the expense of the owner, to place and retain in quarantine all neat cattle, sheep, and other ruminants, and all swine, imported into the United States, at such ports as he may designate for such purpose, and under such conditions as he may by regulation prescribe, respectively, for the several classes of animals above described. For this purpose he may have and maintain possession of all lands, buildings, animals, tools, fixtures, and appurtenances in use on August 3, 1890, for the quarantine of neat cattle, and pur-

chase, construct, or rent as may be necessary, and he may appoint veterinary surgeons, inspectors, officers, and employees by him deemed necessary to maintain such quarantine, and provide for the execution of the other provisions of this subchapter.

(Aug. 30, 1890, ch. 839, §7, 26 Stat. 416.)

REFERENCES IN TEXT

This subchapter, referred to in text, was in the original "this Act", meaning act Aug. 30, 1890, ch. 839, 26 Stat. 415, as amended, which is classified to sections 18, and 101 to 105 of this title and section 181 of Title 19, Customs Duties. For complete classification of this Act to the Code, see Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 104, 136a of this title; title 16 section 1540.

## §103. Importation, except at quarantine ports, prohibited; slaughter of infected animals; appraisal; payment

The importation of all animals described in this subchapter into any port in the United States, except such as may be designated by the Secretary of Agriculture, with the approval of the Secretary of the Treasury, as quarantine stations, is prohibited. The Secretary of Agriculture may cause to be slaughtered such of the animals named in this subchapter as may be, under regulations prescribed by him, adjudged to be infected with any contagious disease, or to have been exposed to infection so as to be dangerous to other animals. The value of animals so slaughtered as being so exposed to infection but not infected may be ascertained by agreement of the Secretary of Agriculture and the owners thereof if practicable; otherwise, by the appraisal by two persons familiar with the character and value of such property, to be appointed by the Secretary of Agriculture, whose decision, if they agree, shall be final; otherwise, the Secretary of Agriculture shall decide between them, and his decision shall be final. The amount of the value thus ascertained shall be paid to the owner thereof out of money in the Treasury appropriated for the use of the Bureau of Animal Industry; but no payment shall be made for any animal imported in violation of the provisions of this subchapter. If any animal subject to quarantine according to the provisions of this subchapter are brought into any port of the United States where no quarantine station is established, the collector of such port shall require the same to be conveyed, by the vessel on which they are imported or are found to the nearest quarantine station, at the expense of the owner.

(Aug. 30, 1890, ch. 839, §8, 26 Stat. 416.)

REFERENCES IN TEXT

This subchapter, referred to in text, was in the original "this Act", meaning act Aug. 30, 1890, ch. 839, 26 Stat. 415, as amended, which is classified to sections 18, and 101 to 105 of this title and section 181 of Title 19, Customs Duties. For complete classification of this Act to the Code, see Tables.

TRANSFER OF FUNCTIONS

Functions of Bureau of Animal Industry transferred to Secretary of Agriculture by Reorg. Plan No. 1 of 1947, §301, eff. July 1, 1947, 12 F.R. 4534, 61 Stat. 952, set out in the Appendix to Title 5, Government Organization and Employees.

For abolition of the offices of collector of customs, see note set out under section 44 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 104, 136a of this title; title 16 section 1540.

## §104. Importation of animals

### (a) In general

The Secretary of Agriculture may by regulation prohibit or restrict the importation or entry of any cattle, sheep, or other ruminants, or swine, that are diseased or infected with any disease, or that have been exposed to an infection, into or through the United States to prevent the dissemination into the United States of a disease.

### (b) Penalties

#### (1) Criminal

Any person who knowingly violates any regulation promulgated by the Secretary pursuant to this section, or any provision of sections 101, 102, 103, and 105 of this title or any regulation promulgated by the Secretary pursuant to such sections, shall be fined under title 18 or imprisoned not more than 1 year, or both.

#### (2) Civil

Any person who violates any such provision or any such regulation may be assessed a civil penalty by the Secretary of Agriculture not exceeding $1,000. The Secretary may issue an order assessing the civil penalty only after notice and an opportunity for an agency hearing on the record. The order shall be treated as a final order reviewable under chapter 158 of title 28. The validity of the order may not be reviewed in an action to collect such civil penalty.

(Aug. 30, 1890, ch. 839, §6, 26 Stat. 416; June 28, 1926, ch. 700, §2, 44 Stat. 775; Feb. 28, 1931, ch. 348, 46 Stat. 1460; July 22, 1954, ch. 558, §32, 68 Stat. 510; Jan. 28, 1956, ch. 12, §1, 70 Stat. 5; Jan. 12, 1983, Pub. L. 97–461, §4, 96 Stat. 2524; Dec. 8, 1993, Pub. L. 103–182, title III, §361(b), 107 Stat. 2122; Dec. 8, 1994, Pub. L. 103–465, title IV, §431(h), 108 Stat. 4969.)

AMENDMENTS

1994—Pub. L. 103–465 amended section generally. Prior to amendment, section read as follows: "The importation of cattle, sheep, and other ruminants, and swine, which are diseased or infected with any disease, or which shall have been exposed to such infection within sixty days next before their exportation, is prohibited, except that the Secretary of Agriculture, in accordance with such regulations as the Secretary may issue, may (1) permit the importation of cattle, sheep, or other ruminants, and swine, from Canada or Mexico, and (2) permit the importation from the British Virgin Islands into the Virgin Islands of the United States, for slaughter only, of cattle that have been infested with or exposed to ticks on being freed from the ticks. Any person who knowingly violates any provision of this section or sections 101, 102, 103, and 105 of this title or any regulation prescribed by the Secretary of Agriculture under any such section shall be guilty of a misdemeanor and shall, on conviction, be punished by a

fine not exceeding $5,000, by imprisonment not exceeding one year, or both. Any person who violates any such provision or any such regulation may be assessed a civil penalty by the Secretary of Agriculture not exceeding $1,000. The Secretary may issue an order assessing such civil penalty only after notice and an opportunity for an agency hearing on the record. Such order shall be treated as a final order reviewable under chapter 158 of title 28. The validity of such order may not be reviewed in an action to collect such civil penalty.''

1993—Pub. L. 103–182 substituted '', except that the Secretary of Agriculture, in accordance with such regulations as the Secretary may issue, may (1) permit the importation of cattle, sheep, or other ruminants, and swine, from Canada or Mexico, and (2) permit the importation from the British Virgin Islands into the Virgin Islands of the United States, for slaughter only, of cattle that have been infested with or exposed to ticks on being freed from the ticks'' for '': *Provided*, That the Secretary of Agriculture, within his discretion and under such regulations as he may prescribe, is authorized to permit the admission from Mexico into the State of Texas of cattle which have been infested with or exposed to ticks upon being freed therefrom, and the admission from the British Virgin Islands into the Virgin Islands of the United States, for slaughter only, of cattle which have been infested with or exposed to ticks upon being freed therefrom''.

1983—Pub. L. 97–461 substituted reference to violation of this section or sections 101, 102, 103, and 105 of this title or any regulation prescribed by the Secretary of Agriculture under any such section, for reference to violation of the foregoing provisions, substituted imprisonment not exceeding one year for imprisonment not exceeding three years, inserted provisions relating to civil penalties, and struck out provision for forfeiture of any vessel used for such importation if the master or owner knew the importation was diseased or had been exposed to infection.

1956—Act Jan. 28, 1956, struck out ''and the admission into the Virgin Islands'' in proviso and limited importation of cattle into Virgin Islands of the United States to cattle from the British Virgin Islands intended for slaughter.

1954—Act July 22, 1954, inserted ''and the admission into the Virgin Islands'' in proviso.

1931—Act Feb. 28, 1931, struck out ''meat'' and substituted ''before their exportation'' for ''before their importation'' in provisions relating to the prohibition of importation of diseased or infected animals.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective, except as otherwise provided, on the date of entry into force of the World Trade Organization Agreement with respect to the United States [Jan. 1, 1995], see section 451 of Pub. L. 103–465, set out as an Effective Date note under section 3601 of Title 19, Customs Duties.

EFFECTIVE DATE OF 1954 AMENDMENT

For effective date of amendment by act July 22, 1954, see section 34 of act July 22, 1954, set out as an Effective Date note under section 1541 of Title 48, Territories and Insular Possessions.

CROSS REFERENCES

Cattle, sheep, swine and meats; importation prohibited in certain cases, see section 1306 of Title 19, Customs Duties.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

## § 105. Inspection of animals

The Secretary of Agriculture may cause careful inspection of any imported animals described in this subchapter, to ascertain whether such animals are infected with contagious diseases or have been exposed to infection so as to be dangerous to other animals, which shall then either be placed in quarantine or dealt with according to the regulations of the Secretary of Agriculture. All food, litter, manure, clothing, utensils, and other appliances that have been so related to such animals on board ship as to be judged liable to convey infection shall be dealt with according to the regulations of the Secretary of Agriculture. The Secretary of Agriculture may cause inspection to be made of all animals described in this subchapter intended for exportation, and provide for the disinfection of all vessels engaged in the transportation thereof, and of all barges or other vessels used in the conveyance of such animals intended for export to the ocean steamer or other vessels, and of all attendants and their clothing, and of all headropes and other appliances used in such exportation, by such orders and regulations as he may prescribe; and if, upon such inspection, any such animals shall be adjudged, under the regulations of the Secretary of Agriculture, to be infected or to have been exposed to infection so as to be dangerous to other animals, the Secretary may prohibit or restrict their placement upon any vessel for exportation; the expense of all the inspection and disinfection provided for in this section to be borne by the owners of the vessels on which such animals are exported.

(Aug. 30, 1890, ch. 839, § 10, 26 Stat. 417; Dec. 8, 1993, Pub. L. 103–182, title III, § 361(c), 107 Stat. 2122; Dec. 8, 1994, Pub. L. 103–465, title IV, § 431(i), 108 Stat. 4969.)

REFERENCES IN TEXT

This subchapter, referred to in text, was in the original ''this Act'', meaning act Aug. 30, 1890, ch. 839, 26 Stat. 415, as amended, which is classified to sections 18 and 101 to 105 of this title and section 181 of Title 19, Customs Duties. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

1994—Pub. L. 103–465 struck out subsec. (a) heading ''In general'', in first sentence, substituted ''The'' for ''Except as provided in subsection (b) of this section, the'' and ''may cause careful inspection of any'' for ''shall cause careful inspection to be made by a suitable officer of all'', in third sentence, substituted ''the Secretary may prohibit or restrict their placement'' for ''they shall not be allowed to be placed'', and struck out heading and text of subsec. (b). Prior to amendment, text read as follows: ''The Secretary of Agriculture, in accordance with such regulations as the Secretary may issue, may waive any provision of subsection (a) of this section in the case of shipments between the United States and Canada or Mexico.''

1993—Pub. L. 103–182 inserted section catchline, designated existing provisions as subsec. (a), inserted heading and exception to subsec. (b), and added subsec. (b).

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective, except as otherwise provided, on the date of entry into force of the World Trade Organization Agreement with respect to the United States [Jan. 1, 1995], see section 451 of Pub. L. 103–465, set out as an Effective Date note under section 3601 of Title 19, Customs Duties.

CROSS REFERENCES

Inspection of animals for export, see section 612 et seq. of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 104, 136a of this title; title 16 section 1540.

### §§ 106, 107. Omitted

CODIFICATION

Sections, acts Aug. 10, 1917, ch. 52, § 9, 40 Stat. 275; Nov. 21, 1918, ch. 212, § 3, 40 Stat. 1048, related to slaughter of tick-infested cattle. Section 12 of act Aug. 10, 1917, provided that the act should cease to be in effect when the national emergency resulting from World War I had passed.

## SUBCHAPTER III—PREVENTION OF INTRODUCTION AND SPREAD OF CONTAGION

### § 111. Regulations to prevent contagious diseases

The Secretary of Agriculture shall have authority to make such regulations and take such measures as he may deem proper to prevent the introduction or dissemination of the contagion of any contagious, infectious, or communicable disease of animals and/or live poultry from a foreign country into the United States or from one State or Territory of the United States or the District of Columbia to another, and to seize, quarantine, and dispose of any hay, straw, forage, or similar material, or any meats, hides, or other animal products coming from an infected foreign country to the United States, or from one State or Territory or the District of Columbia in transit to another State or Territory or the District of Columbia whenever in his judgment such action is advisable in order to guard against the introduction or spread of such contagion.

(Feb. 2, 1903, ch. 349, § 2, 32 Stat. 792; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 22, 1954, ch. 558, § 33, 68 Stat. 510; Jan. 28, 1956, ch. 12, § 2, 70 Stat. 5.)

AMENDMENTS

1956—Act Jan. 28, 1956, struck out proviso ''that no such regulations or measures shall pertain to the introduction of live poultry into the Virgin Islands of the United States''.

1954—Act July 22, 1954, inserted proviso containing an exception with respect to admission of live poultry into the Virgin Islands.

1928—Act Feb. 7, 1928, inserted ''and/or live poultry''.

EFFECTIVE DATE OF 1954 AMENDMENT

For effective date of amendment by act July 22, 1954, see section 34 of act July 22, 1954, set out as an Effective Date note under section 1541 of Title 48, Territories and Insular Possessions.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114g, 122, 136a of this title; title 16 section 1540.

### § 112. Investigations as to pleuropneumonia, and other diseases; regulations

In order to promote the exportation of livestock and/or live poultry from the United States the Secretary of Agriculture shall make special investigation as to the existence of pleuropneumonia, or any contagious, infectious, or communicable disease, along the dividing lines between the United States and foreign countries, and along the lines of transportation from all parts of the United States to ports from which livestock and/or live poultry are exported, and shall, from time to time, establish such regulations concerning the exportation and transportation of livestock and/or live poultry as the results of said investigations may require.

(May 29, 1884, ch. 60, § 4, 23 Stat. 32; Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

CODIFICATION

Originally this section and sections 113, 114, 117, 119, 120, and 130 of this title read ''Commissioner'' instead of ''Secretary'' of Agriculture, and this section contained between the words ''and'' and ''shall,'' the additional words ''make report of the results of such investigation to the Secretary of the Treasury, who''.

Designation of office of Commissioner of Agriculture changed by change of department into an executive department under a Secretary of Agriculture, by act Feb. 9, 1889, ch. 122, § 1, 25 Stat. 659, set out as section 2202 of Title 7, Agriculture. Authority granted to Commissioner by act May 29, 1884, vested in Secretary of Agriculture by a provision of act July 14, 1890, ch. 707, 26 Stat. 288, set out as section 2205 of Title 7.

Powers conferred on Secretary of the Treasury by act May 29, 1884, were conferred on Secretary of Agriculture by part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 113, 120, and 121 of this title.

AMENDMENTS

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock'' wherever appearing.

SHORT TITLE

Act Feb. 2, 1903, classified to sections 112 and 120 to 122 of this title, entitled, ''An act to enable the Secretary of Agriculture to more effectually suppress and prevent the spread of contagious and infectious diseases of live stock, and for other purposes'' is popularly known as the Cattle Contagious Diseases Act of 1903.

Act May 29, 1884, entitled, ''An act for the establishment of a Bureau of Animal Industry, to prevent the exportation of diseased cattle, and to provide means for the suppression and extirpation of pleuro-pneumonia and other contagious diseases among domestic animals'' is popularly known as the Animal Industry Act. The Act is classified to sections 112, 113 to 114a–1, 115, 116, 117 to 120, and 130 of this title and section 391 of Title 7, Agriculture.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119, 136a of this title; title 16 section 1540.

### § 112a. Omitted

CODIFICATION

Section, act Feb. 7, 1928, ch. 30, 45 Stat. 59, amended acts May 29, 1884, ch. 60, 22 Stat. 31; Feb. 2, 1903, ch. 349, 32 Stat. 791; and Mar. 3, 1905, ch. 1496, 33 Stat. 1264, to include live poultry in their provisions, added ''and/or live poultry'' following ''live stock'' wherever the term ''live stock'' appeared, and extended the penalty provisions of said acts to live poultry.

### § 113. Measures to prevent exportation of diseased livestock and live poultry

In order to prevent the exportation from any port of the United States to any port in a foreign country of livestock and/or live poultry affected with any contagious, infectious, or communicable disease, and especially pleuropneumonia, the Secretary of Agriculture is authorized to take such steps and adopt such measures,

not inconsistent with the provisions of this Act, as he may deem necessary.

(May 29, 1884, ch. 60, § 5, 23 Stat. 32; Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

REFERENCES IN TEXT

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, as amended, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables.

CODIFICATION

Section is comprised of part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 112, 120, and 121 of this title.

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see note set out under section 112 of this title.

AMENDMENTS

1928—Act Feb. 7, 1928, inserted ''and/or live poultry''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

## § 113a. Establishment of research laboratories for foot-and-mouth disease and other animal diseases; research contracts; employment of technicians and scientists; appropriations

The Secretary of Agriculture is authorized to establish research laboratories, including the acquisition of necessary land, buildings, or facilities, and also the making of research contracts under the authority contained in section 427i(a) of title 7, for research and study, in the United States or elsewhere, of foot-and-mouth disease and other animal diseases which in the opinion of the Secretary constitute a threat to the livestock industry of the United States: *Provided*, That no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States (except coastal islands separated therefrom by water navigable for deep-water navigation and which shall not be connected with the mainland by any tunnel) unless the Secretary determines that it is necessary and in the public interest for the conduct of research and study in the United States (except at Brookhaven National Laboratory in Upton, New York) and issues a permit under such rules as the Secretary shall promulgate to protect animal health, except that the Secretary of Agriculture may transport said virus in the original package across the mainland under adequate safeguards, and except further, that in the event of outbreak of foot-and-mouth disease in this country, the Secretary of Agriculture may, at his discretion, permit said virus to be brought into the United States under adequate safeguards. To carry out the provisions of this section, the Secretary is authorized to employ technical experts or scientists: *Provided*, That the number so employed shall not exceed five and that the maximum compensation for each shall not exceed the highest rate of grade 18 of the General Schedule. There is authorized to be appropriated such sums as Congress may deem necessary; in addition, the Secretary is authorized to utilize in carrying out this section, funds otherwise available for the control or eradication of such diseases.

(May 29, 1884, ch. 60, § 12, as added Apr. 24, 1948, ch. 229, 62 Stat. 198; amended July 31, 1956, ch. 804, title I, § 119, 70 Stat. 742; July 31, 1958, Pub. L. 85–573, 72 Stat. 454; Oct. 11, 1962, Pub. L. 87–793, § 1001(e), 76 Stat. 864; Aug. 14, 1964, Pub. L. 88–426, title III, § 305(1), 78 Stat. 422; Nov. 28, 1990, Pub. L. 101–624, title XVI, § 1618(b), 104 Stat. 3733.)

CODIFICATION

Provisions that authorized the Secretary to employ technical experts and scientists ''without regard to the Classification Act'', meaning the Classification Act of 1923, were omitted as obsolete. Sections 1202 and 1204 of the Classification Act of 1949, 63 Stat. 972, 973, repealed the 1923 Act and all laws or parts of laws inconsistent with the 1949 Act. While section 1106(a) of the 1949 Act provided that references in other laws to the 1923 Act should be held and considered to mean the 1949 Act, it did not have the effect of continuing the exception contained in this section because of section 1106(b) which provided that the application of the 1949 Act to any position, officer, or employee shall not be affected by section 1106(a). The Classification Act of 1949 was repealed by Pub. L. 89–554, Sept. 6, 1966, § 8(a), 80 Stat. 632 (the first section of which revised and enacted Title 5, Government Organization and Employees, into law). Section 5102 of Title 5 contains the applicability provisions of the 1949 Act, and section 5103 of Title 5 authorizes the Office of Personnel Management to determine the applicability to specific positions and employees.

AMENDMENTS

1990—Pub. L. 101–624 substituted ''United States (except'' for ''United States except'' and ''tunnel) unless the Secretary determines that it is necessary and in the public interest for the conduct of research and study in the United States (except at Brookhaven National Laboratory in Upton, New York) and issues a permit under such rules as the Secretary shall promulgate to protect animal health,'' for ''tunnel, and''.

1962—Pub. L. 87–793 substituted ''shall not exceed the highest rate of grade 18 of the General Schedule'' for ''shall not exceed $19,000 per annum''.

1958—Pub. L. 85–573 inserted in proviso clause of first sentence the exception clause respecting transportation of virus in original package across mainland under adequate safeguards.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–793 effective on first day of first pay period which begins on or after Oct. 11, 1962.

REPEALS

Act July 31, 1956, ch. 804, title I, § 119, 70 Stat. 742, which increased the maximum compensation of technical experts or scientists, was repealed by Pub. L. 88–426, title III, § 305(1), Aug. 14, 1964, 78 Stat. 422.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119, 136a of this title; title 16 section 1540.

### § 114. Regulations for suppression of diseases; cooperation of States and Territories

It shall be the duty of the Secretary of Agriculture to prepare such rules and regulations as he may deem necessary for the speedy and effectual suppression and extirpation of pleuropneumonia and other dangerous, contagious, infectious, and communicable diseases, and to certify such rules and regulations to the executive authority of each State and Territory, and invite said authorities to cooperate in the execution and enforcement of the provisions of this Act. Whenever the plans and methods of the Secretary of Agriculture shall be accepted by any State or Territory in which pleuropneumonia or other contagious, infectious, or communicable disease is declared to exist, or such State or Territory shall have adopted plans and methods for the suppression and extirpation of said diseases, and such plans and methods shall be accepted by the Secretary of Agriculture, and whenever the governor of a State or other properly constituted authorities signify their readiness to cooperate for the extinction of any contagious, infectious, or communicable disease in conformity with the provisions of this Act, the Secretary of Agriculture is authorized to expend so much of the money appropriated for carrying out the provisions of this Act as may be necessary in such investigations, and in such disinfection and quarantine measures as may be necessary to prevent the spread of the disease from one State or Territory into another.

(May 29, 1884, ch. 60, § 3, 23 Stat. 32.)

REFERENCES IN TEXT

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, as amended, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables.

CODIFICATION

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see note set out under section 112 of this title.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 118, 119, 136a of this title; title 16 section 1540.

### § 114a. Control and eradication of diseases; cooperation of States and farmers' associations; purchase and destruction of diseased animals; "State" defined

The Secretary of Agriculture, either independently or in cooperation with States or political subdivisions thereof, farmers' associations and similar organizations, and individuals, is authorized to control and eradicate any communicable diseases of livestock or poultry, including, but not limited to, tuberculosis and paratuberculosis of animals, avian tuberculosis, brucellosis of domestic animals, southern cattle ticks, hog cholera and related swine diseases, scabies in sheep and cattle, dourine in horses, scrapie and blue tongue in sheep, incipient or potentially serious minor outbreaks of diseases of animals, and contagious or infectious diseases of animals (such as foot-and-mouth disease, rinderpest, and contagious pleuropneumonia) which in the opinion of the Secretary constitute an emergency and threaten the livestock industry of the country, including the payment of claims growing out of destruction of animals (including poultry), and of materials, affected by or exposed to any such disease, in accordance with such regulations as the Secretary may prescribe. The Secretary of Agriculture is authorized to prescribe and collect fees to recover the costs of carrying out the provisions of this section which relate to veterinary diagnostics. As used in this section, the term ''State'' includes the District of Columbia, Puerto Rico, and the Territories and possessions of the United States.

(May 29, 1884, ch. 60, § 11, as added Sept. 21, 1944, ch. 412, title I, § 101(a), 58 Stat. 734; amended Oct. 30, 1951, ch. 637, § 1, 65 Stat. 693; Aug. 8, 1953, ch. 381, 67 Stat. 493; Aug. 3, 1956, ch. 950, § 2, 70 Stat. 1032; July 2, 1962, Pub. L. 87–518, § 7, 76 Stat. 131; Nov. 28, 1990, Pub. L. 101–624, title XXV, § 2509(c)(2), 104 Stat. 4071.)

PRIOR PROVISIONS

A prior section 11 of act May 29, 1884, required annual reports to Congress concerning the suppression of contagious diseases among domestic animals, and was classified to section 560 of former Title 5, prior to repeal by act May 29, 1928, ch. 901, § 1, 45 Stat. 993.

AMENDMENTS

1990—Pub. L. 101–624 inserted after first sentence ''The Secretary of Agriculture is authorized to prescribe and collect fees to recover the costs of carrying out the provisions of this section which relate to veterinary diagnostics.''

1962—Pub. L. 87–518 inserted ''any communicable diseases of livestock or poultry, including, but not limited to,'' after ''eradicate''.

1956—Act Aug. 3, 1956, authorized payment of claims for destruction of material affected or exposed to disease.

1953—Act Aug. 8, 1953, provided for control and eradication of scrapie and blue tongue in sheep, as well as incipient and potentially serious minor outbreaks of diseases of animals.

1951—Act Oct. 30, 1951, substituted ''brucellosis of domestic animals'' for ''Bang's disease of cattle''.

APPROPRIATIONS

Section 101(g) of act Sept. 21, 1944, provided that Congress may appropriate such funds as are necessary to accomplish the purpose of this section.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 114c, 114g, 118, 119, 136a of this title; title 16 section 1540.

### § 114a–1. Interstate movement of domestic animals reacting to tests for brucellosis; immediate slaughter; rules and regulations

Domestic animals which have reacted to a test recognized by the Secretary of Agriculture for paratuberculosis or which, never having been vaccinated for brucellosis, have reacted to a test recognized by the Secretary of Agriculture for brucellosis, may be shipped, transported, or otherwise moved from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia for imme-

diate slaughter in accordance with such rules and regulations as the Secretary of Agriculture may prescribe to prevent the dissemination of said diseases from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia. The Secretary of Agriculture may, in his discretion and under such rules and regulations as he may prescribe, permit domestic animals which have been moved from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, for breeding purposes, and which, subsequent to such movement, have reacted to a test for brucellosis or paratuberculosis recognized by the Secretary of Agriculture, to be reshipped in interstate commerce to the original owner at the point of origin.

(May 29, 1884, ch. 80, § 13, as added Oct. 30, 1951, ch. 637, § 2, 65 Stat. 693.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119, 136a of this title; title 16 section 1540.

### § 114b. Cooperation in animal disease control

The Secretary of Agriculture is authorized to cooperate with the Governments of foreign countries, and with foreign or international organizations or associations in carrying out operations or measures to eradicate, suppress, or control, or to prevent or retard, any communicable disease of animals or vectors thereof, including but not limited to foot-and-mouth disease, rinderpest, or screwworm in such countries where he deems such action necessary to protect the livestock, poultry, and related industries of the United States. In performing the operations or measures authorized in sections 114b to 114d–1 of this title, the Governments of such countries shall be responsible for the authority necessary to carry out such operations or measures on all lands and properties therein and for such other facilities and means as in the discretion of the Secretary of Agriculture are necessary. The measure and character of cooperation carried out under said sections on the part of the United States and on the part of the Governments of such countries, including the expenditure or use of funds appropriated pursuant to said sections, shall be such as may be prescribed by the Secretary of Agriculture. Arrangements for the cooperation authorized by said sections shall be made through and in consultation with the Secretary of State. The authority contained in said sections is in addition to and not in substitution for the authority of existing law.

(Feb. 28, 1947, ch. 8, § 1, 61 Stat. 7; July 27, 1966, Pub. L. 89–521, § 1, 80 Stat. 330; Nov. 5, 1971, Pub. L. 92–152, § 1, 85 Stat. 418; Mar. 15, 1976, Pub. L. 94–231, § 3, 90 Stat. 216; Mar. 15, 1990, Pub. L. 101–255, § 1(1), 104 Stat. 114; Nov. 28, 1990, Pub. L. 101–624, title XXV, § 2505, 104 Stat. 4068.)

AMENDMENTS

1990—Pub. L. 101–624 substituted ''foreign countries'' for ''Mexico, Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, Belize, Panama, Colombia, and Canada, the Bahama Islands, the Greater Antilles, and the Lesser Antilles'' and inserted ''foreign or'' before ''international''.

Pub. L. 101–255 inserted section catchline and substituted ''screwworm'' for ''screw-worm'' in text.

1976—Pub. L. 94–231 substituted ''Belize'' for ''British Honduras'', inserted '', the Bahama Islands, the Greater Antilles, and the Lesser Antilles, and with international organizations or associations'' after ''Canada'', and inserted ''or vectors thereof'' after ''any communicable disease of animals''.

1971—Pub. L. 92–152 made provisions applicable to and authorized cooperation of Secretary of Agriculture with Governments of Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, British Honduras, Panama, Columbia, and Canada, directed operations and measures to be taken against communicable diseases of animals, and included protection of poultry within its scope.

1966—Pub. L. 89–521 authorized the Secretary of Agriculture to cooperate in screw-worm eradication in Mexico.

SHORT TITLE

Section 6 of act Feb. 28, 1947, as added by Pub. L. 101–255, § 1(6), Mar. 15, 1990, 104 Stat. 114, provided that: ''This Act [enacting this section and sections 114c to 114d–1 of this title and provisions set out as a note under this section] may be referred to as the 'Animal Disease Control Cooperation Act of 1947'.''

APPROPRIATIONS

Act Mar. 27, 1947, ch. 22, 61 Stat. 24, provided for an appropriation of $9,000,000 to carry out the provisions of this section during fiscal year 1947.

Section 4 of act Feb. 28, 1947, as amended by Pub. L. 101–255, § 1(4), Mar. 15, 1990, 104 Stat. 114, provided: ''There are authorized to be appropriated such sums as may be necessary to carry out this Act [sections 114b to 114d of this title].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114c, 114d, 114d–1, 129, 136a of this title; title 7 section 147b; title 16 section 1540.

### § 114c. Use of funds

For purposes of sections 114a, and 114b to 114d–1 of this title, insofar as sections 114b to 114d–1 of this title relate to diseases which in the opinion of the Secretary constitute an emergency and threaten the livestock industry of the country, funds appropriated pursuant thereto may also be used for the purchase or hire of passenger motor vehicles and aircraft, for printing and binding without regard to section 501 of title 44, for personal services in the District of Columbia and elsewhere without regard to the limitations contained in section 607(g) of the Federal Employees Pay Act of 1945, as amended, including the employment of civilian nationals of Mexico, Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, British Honduras, Panama, Columbia, and Canada, and for the construction and operation of research laboratories, quarantine stations and other buildings and facilities.

(Feb. 28, 1947, ch. 8, § 2, 61 Stat. 7; Aug. 3, 1956, ch. 950, § 3, 70 Stat. 1033; Nov. 5, 1971, Pub. L. 92–152, § 2, 85 Stat. 419; Mar. 15, 1990, Pub. L. 101–255, § 1(2), 104 Stat. 114.)

REFERENCES IN TEXT

Section 607(g) of the Federal Employees Pay Act of 1945, as amended [former 5 U.S.C. 947(g)], referred to in text, was repealed by act Sept. 12, 1950, ch. 946, title III, § 301(85), 64 Stat. 843.

CODIFICATION

''Section 501 of title 44'' substituted in text for ''section 87 of the Act of January 12, 1895, or section 11 of

the Act of March 1, 1919 (U.S.C., title 44, sec. 111)'' on authority of Pub. L. 90–620, § 2(b), Oct. 22, 1968, 82 Stat. 1305, the first section of which enacted Title 44, Public Printing and Documents.

AMENDMENTS

1990—Pub. L. 101–255 inserted section catchline.

1971—Pub. L. 92–152 provided for use of funds for employment of civilian nationals of Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, British Honduras, Panama, Columbia, and Canada.

1956—Act Aug. 3, 1956, inserted ''and section 114a of this title, insofar as sections 114b–114d of this title relate to diseases which in the opinion of the Secretary constitute an emergency and threaten the livestock industry of the country'' in first sentence.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114b, 114d–1, 129, 136a of this title; title 16 section 1540.

### § 114d. Sale of sterile screwworms

#### (a) In general

Notwithstanding section 114b of this title, the Secretary of Agriculture may, independently or in cooperation with any foreign government or any international organization or association, produce and sell sterile screwworms to any foreign government or to any international organization or association, if the Secretary determines that the protection of livestock and related industries of the United States will not be adversely affected by such production and sale.

#### (b) Terms of sale

The Secretary may provide for the sale of screwworms under subsection (a) of this section under such terms and conditions as the Secretary considers appropriate.

#### (c) Deposit of proceeds

##### (1) Independent sales

If the Secretary independently produces and sells screwworms under subsection (a) of this section, the proceeds of such sales shall be deposited in the Treasury of the United States and be credited to the appropriation from which the operating expenses of the facility producing the screwworms have been paid.

##### (2) Cooperative sales

If the Secretary produces and sells screwworms in cooperation with a foreign government or an international organization or association, the proceeds of such sale shall be divided between the United States and such government, organization, or association, as determined by the Secretary, and the United States portion of such proceeds shall be deposited into the Treasury of the United States and be credited to the appropriation from which the operating expenses of the facility producing the screwworms have been paid.

(Feb. 28, 1947, ch. 8, § 3, as added Mar. 15, 1990, Pub. L. 101–255, § 1(3), 104 Stat. 114.)

PRIOR PROVISIONS

A prior section 114d, act Feb. 28, 1947, ch. 8, § 3, 61 Stat. 8, related to reports by Secretary of Agriculture to Congress with respect to activities carried on under sections 114b and 114c of this title, prior to repeal by Pub. L. 86–533, § 1(20), June 29, 1960, 74 Stat. 249.

### § 114d–1. Cooperation with public and private entities

In carrying out sections 114b to 114d–1 of this title the Secretary of Agriculture is further authorized to cooperate with other public and private organizations and individuals.

(Feb. 28, 1947, ch. 8, § 5, as added July 27, 1966, Pub. L. 89–521, § 2, 80 Stat. 330; amended Mar. 15, 1990, Pub. L. 101–255, § 1(5), 104 Stat. 114.)

AMENDMENTS

1990—Pub. L. 101–255 inserted section catchline.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114b, 114c, 129, 136a of this title; title 16 section 1540.

### §§ 114d–2 to 114d–6. Repealed. Pub. L. 92–152, § 3, Nov. 5, 1971, 85 Stat. 419

Section 114d–2, Pub. L. 90–388, § 1, July 6, 1968, 82 Stat. 294, provided for cooperation with Central America in control and eradication of foot-and-mouth disease or rinderpest. See section 114b of this title.

Section 114d–3, Pub. L. 90–388, § 2, July 6, 1968, 82 Stat. 294, provided for uses of funds. See section 114c of this title.

Section 114d–4, Pub. L. 90–388, § 3, July 6, 1968, 82 Stat. 294, defined governments of Central America. See sections 114b and 114c of this title.

Section 114d–5, Pub. L. 90–388, § 4, July 6, 1968, 82 Stat. 294, provided for cooperation with public and private organizations and individuals. See section 114d–1 of this title.

Section 114d–6, Pub. L. 90–388, § 5, July 6, 1968, 82 Stat. 294, provided for authorization of appropriations. See Appropriations note set out under section 114b of this title.

### § 114e. Control and eradication of cattle grubs; research and investigations

In order to protect, promote, and conserve livestock and livestock products and to minimize losses, the Secretary of Agriculture, either independently or in cooperation with States or subdivisions thereof, farmers' associations, and other organizations and individuals, it[1] is authorized to increase and intensify research and investigations into problems and methods relating to the eradication of cattle grubs and to undertake measures to eradicate these parasites.

(June 16, 1948, ch. 477, § 1, 62 Stat. 458.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114f, 136a of this title; title 16 section 1540.

### § 114f. "State" defined; authorization of appropriations

As used in section 114e of this title, the term ''State'' includes the District of Columbia and the Territories and possessions of the United States. There is authorized to be appropriated such sums as may be necessary to carry out section 114e of this title. Funds appropriated pursuant to this section shall be expended in accordance with procedures prescribed by the Secretary.

(June 16, 1948, ch. 477, § 2, 62 Stat. 458.)

[1] So in original.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

### § 114g. Hog cholera eradication program

In order to safeguard the health of the swine herds of the Nation, to prevent the spread of hog cholera, to decrease substantially the estimated $50,000,000 annual loss from hog cholera, to expand export markets for pork and pork products now restricted on account of hog cholera, and to otherwise protect the public interest, the Secretary of Agriculture is directed (1) to initiate a national hog cholera eradication program in cooperation with the several States under the provisions of section 114a of this title and related legislation, and (2) to prohibit or restrict, pursuant to the authority vested in him under the provisions of section 111 of this title the interstate movement of virulent hog cholera virus or other hog cholera virus to the extent he determines necessary in order to effectuate such eradication program.

(Pub. L. 87–209, § 1, Sept. 6, 1961, 75 Stat. 481.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114h, 136a of this title; title 16 section 1540.

### § 114h. Advisory committee

#### (a) Establishment; membership

The Secretary of Agriculture is authorized and directed to establish an advisory committee composed of (1) eleven members selected from representatives of the swine and related industries, State and local government agencies, professional and scientific groups, and the general public, and (2) one member selected from the officers and employees of the Department of Agriculture who shall serve as chairman of the Committee. The Committee shall meet at the call of the Secretary.

#### (b) Functions

It shall be the function of the Committee to advise the Secretary with respect to the initiation of the national hog cholera eradication program referred to in section 114g of this title, and with respect to the development of plans and procedures for carrying out such program.

#### (c) Employment status; expenses

Committee members other than the chairman shall not be deemed to be employees of the United States and shall not be entitled to compensation, but the Secretary is authorized to pay their travel and subsistence expenses (or per diem in lieu thereof) in connection with their attendance at meetings of the Committee.

(Pub. L. 87–209, § 2, Sept. 6, 1961, 75 Stat. 481.)

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

### § 114i. Pseudorabies eradication

#### (a) Findings

Congress finds that efforts to eradicate pseudorabies in United States swine populations by the Department of Agriculture in cooperation with State agencies and the pork industry have a high priority and should be continued until pseudorabies is completely eradicated in the United States.

#### (b) Establishment of program

The Secretary of Agriculture shall establish and carry out a program for the eradication of pseudorabies in United States swine populations.

#### (c) Use of funds for testing and control of pseudorabies

The Secretary shall ensure that not less than 65 percent of the funds appropriated for the program established under subsection (b) of this section shall be used for testing and screening of animals and for other purposes directly related to the eradication or control of pseudorabies. This requirement on the use of appropriated funds for this program shall not be implemented in a manner that would adversely affect any other animal or plant disease or pest eradication or control program.

#### (d) Authorization of appropriations

There are authorized to be appropriated for each of the fiscal years 1991 through 1995 such sums as may be necessary for the purpose of carrying out the program established under subsection (b) of this section.

(Pub. L. 101–624, title XXV, § 2506, Nov. 28, 1990, 104 Stat. 4068.)

### § 115. Transportation of diseased livestock and live poultry prohibited

No railroad company within the United States, or the owners or masters of any steam or sailing or other vessel or boat, shall receive for transportation or transport from one State or Territory to another, or from any State into the District of Columbia, or from the District into any State, any livestock and/or live poultry affected with any contagious, infectious, or communicable disease, and especially the disease known as pleuropneumonia; nor shall any person, company, or corporation deliver for such transportation to any railroad company, or master or owner of any boat or vessel, any livestock and/or live poultry, knowing them to be affected with any contagious, infectious, or communicable disease; nor shall any person, company, or corporation drive on foot, or transport in private conveyance from one State or Territory to another, or from any State into the District of Columbia, or from the District into any State, any livestock and/or live poultry, knowing them to be affected with any contagious, infectious, or communicable disease, and especially the dis-

ease known as pleuropneumonia: *Provided*, That such livestock or poultry may be so delivered and received for such transportation and so transported and moved if the Secretary of Agriculture determines that such action will not endanger the livestock or poultry of the United States and authorizes such action, and such delivery, receipt, transportation, and movement are made in strict compliance with such rules and regulations as the Secretary of Agriculture may prescribe to protect the livestock and poultry of the United States.

(May 29, 1884, ch. 60, §6, 23 Stat. 32; June 28, 1926, ch. 700, §1, 44 Stat. 774; Feb. 7, 1928, ch. 30, 45 Stat. 59; Oct. 9, 1962, Pub. L. 87–763, 76 Stat. 762.)

CODIFICATION

Act May 29, 1884, as amended by act June 28, 1926, also contained the following proviso: ''That until May 1, 1928, cattle infested with or exposed to cattle fever ticks may be shipped in interstate commerce for immediate slaughter after one dipping in accordance with such regulations as the Secretary of Agriculture may prescribe.''

AMENDMENTS

1962—Pub. L. 87–763 inserted proviso permitting such livestock or poultry to be delivered and received for transportation and so transported and moved if the Secretary determines that such action will not endanger the livestock or poultry of the United States and authorizes such action, and such delivery, receipt, transportation, and movement are made in strict compliance with such rules and regulations as the Secretary may prescribe.

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock'' wherever appearing.

1926—Act June 28, 1926, struck out provision deeming splenetic or Texas fever not a communicable disease as to cattle unloaded only to be fed and watered on the way by rail to market for slaughter.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 117, 118, 119, 136a of this title; title 16 section 1540.

### §116. Shipment of certain cattle excepted

Cattle which have reacted to the tuberculin test may be shipped, transported, or moved from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, for immediate slaughter, in accordance with such rules and regulations as shall be prescribed by the Secretary of Agriculture. The said Secretary of Agriculture may, in his discretion, and under such rules and regulations as he may prescribe, permit cattle which have been shipped for breeding or feeding purposes from one State, Territory, or the District of Columbia to another State, Territory, or the District of Columbia, and which have reacted to the tuberculin test subsequent to such shipment, to be reshipped in interstate commerce to the original owner.

(May 29, 1884, ch. 60, 23 Stat. 31; May 31, 1920, ch. 217, 41 Stat. 699.)

AMENDMENTS

1920—Act May 31, 1920, amended act May 29, 1884, without amending any particular section thereof, by enacting provisions set out as this section. For classification of act May 29, 1884, to the Code, see Short Title note set out under section 112 of this title and Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

### §117. Penalties for transportation of diseased livestock or live poultry

**(a) Criminal penalty**

Any person or persons operating any railroad, or master or owner of any boat or vessel, or owner or custodian of, or person having control over, cattle or other livestock or live poultry who shall knowingly violate the provisions of section 115 of this title or the rules and regulations prescribed by the Secretary of Agriculture under such section shall be guilty of a misdemeanor and, upon conviction, shall be punished by a fine of not more than $5,000 or by imprisonment for not more than one year, or by both such fine and imprisonment.

**(b) Civil penalty**

Any person or persons operating any railroad, or master or owner of any boat or vessel, or owner or custodian of, or person having control over, cattle or other livestock or live poultry who shall violate the provisions of section 115 of this title or the rules and regulations prescribed by the Secretary of Agriculture under such section may be assessed a civil penalty by the Secretary of not more than $1,000. The Secretary may issue an order assessing such civil penalty only after notice and an opportunity for an agency hearing on the record. Such order shall be treated as a final order reviewable under chapter 158 of title 28. The validity of such order may not be reviewed in an action to collect such civil penalty.

(May 29, 1884, ch. 60, §7, 23 Stat. 32; Feb. 7, 1928, ch. 30, 45 Stat. 59; Oct. 10, 1978, Pub. L. 95–439, §1, 92 Stat. 1061; Jan. 12, 1983, Pub. L. 97–461, §5, 96 Stat. 2524.)

AMENDMENTS

1983—Pub. L. 97–461 designated existing provisions as subsec. (a), inserted ''or the rules and regulations prescribed by the Secretary of Agriculture under such section'' after ''title'', and added subsec. (b).

1978—Pub. L. 95–439 struck out provision requiring the Secretary of Agriculture to notify in writing the proper officials of any railroad, steamboat, or other transportation company doing business in an infected area of the existence of a contagion and to publish in newspapers the existence of a contagion.

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119, 136a of this title; title 16 section 1540.

### §118. Duty of United States attorneys

It shall be the duty of the several United States attorneys to prosecute all violations of this Act which shall be brought to their notice or knowledge by any person making the complaint under oath; and the same shall be heard before any district court of the United States or Territorial court holden within the district in which such violation of this Act has been committed.

(May 29, 1884, ch. 60, §9, 23 Stat. 33; June 25, 1948, ch. 646, §1, 62 Stat. 909.)

REFERENCES IN TEXT

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, as amended, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables.

CHANGE OF NAME

Act June 25, 1948, eff. Sept. 1, 1948, substituted ''United States attorneys'' for ''United States district attorneys''. See section 541 of Title 28, Judiciary and Judicial Procedure.

REPEALS

Act June 25, 1948, ch. 646, § 39, 62 Stat. 992, repealed act Mar. 3, 1911, ch. 231, § 289, 36 Stat. 1167, formerly cited as a credit to this section.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

FEDERAL RULES OF CRIMINAL PROCEDURE

Special venue provisions of section as not affected by rule 18, see Notes of Advisory Committee on Rules set out under rule 18, Title 18, Appendix, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

## § 119. Agents to examine and report on methods of treatment of animals, and means for suppression of diseases

The Secretary of Agriculture is authorized to appoint two competent agents, who shall be practical stock raisers or experienced business men familiar with questions pertaining to commercial transactions in livestock and/or live poultry, whose duty it shall be, under the instructions of the said Secretary of Agriculture, to examine and report upon the best methods of treating, transporting, and caring for animals, and the means to be adopted for the suppression and extirpation of contagious pleuropneumonia, and to provide against the spread of other dangerous contagious, infectious, and communicable diseases. The compensation of said agents shall be at the rate of $10 per diem, with all necessary expenses, while engaged in the actual performance of their duties under this Act, when absent from their usual place of business or residence as such agent.

(May 29, 1884, ch. 60, § 2, 23 Stat. 31; Feb. 9, 1889, ch. 122, § 1, 25 Stat. 659; July 14, 1890, ch. 707, 26 Stat. 288; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

REFERENCES IN TEXT

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, as amended, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables.

CODIFICATION

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see note set out under section 112 of this title.

AMENDMENTS

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 136a of this title; title 16 section 1540.

## § 120. Regulation of exportation and transportation of infected livestock and live poultry

In order to enable the Secretary of Agriculture to effectually suppress and extirpate contagious pleuropneumonia, foot-and-mouth disease, and other dangerous contagious, infectious, and communicable diseases in cattle and other livestock and/or live poultry, and to prevent the spread of such diseases, he is authorized and directed from time to time to establish such rules and regulations concerning the exportation and transportation of livestock and/or live poultry from any place within the United States where he may have reason to believe such diseases may exist into and through any State or Territory, and into and through the District of Columbia and to foreign countries as he may deem necessary, and all such rules and regulations shall have the force of law.

(May 29, 1884, ch. 60, §§ 4, 5, 23 Stat. 32; Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

CODIFICATION

Section is comprised of part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 112, 113, and 121 of this title. The words ''including the Indian Territory'' which followed the word ''Territory'' in the original text of this section were omitted as obsolete.

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see note set out under section 112 of this title.

AMENDMENTS

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock'' wherever appearing.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119, 121, 122, 136a of this title; title 16 section 1540.

## § 121. Shipments from areas suspected infected; control of animals and live poultry

Whenever any inspector or assistant inspector of the Bureau of Animal Industry shall issue a certificate showing that such officer had inspected any cattle or other livestock and/or live poultry which were about to be shipped, driven, or transported from such locality to another as stated in section 120 of this title, and had found them free from Texas or splenetic fever infection, pleuropneumonia, foot-and-mouth disease, or any other infectious, contagious, or communicable disease, such animals, so inspected and certified, may be shipped, driven, or transported from such place into and through any State or Territory, and into and through the District of Columbia, or they may be exported from the United States without further inspection or the exaction of fees of any kind, except such as may at any time be ordered or exacted by the Secretary of Agriculture; and all such animals shall at all times be under the control and supervision of the Bureau of Animal Industry of the Agricultural Department for the purposes of such inspection.

(Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

CODIFICATION

Section is comprised of part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 112, 113 and 120 of this title.

The words ''including the Indian territory'' which followed ''Territory'' in the original text of this section were omitted as obsolete.

AMENDMENTS

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 122, 136a of this title; title 16 section 1540.

### § 122. Offenses; penalty

Any person, company, or corporation knowingly violating the provisions of this Act or the orders or regulations made in pursuance thereof shall be guilty of a misdemeanor, and on conviction shall be punished by a fine of not less than one hundred dollars nor more than five thousand dollars, or by imprisonment not more than one year, or by both such fine and imprisonment. Any person, company, or corporation violating such provisions, orders, or regulations may be assessed a civil penalty by the Secretary of Agriculture of not more than one thousand dollars. The Secretary may issue an order assessing such civil penalty only after notice and an opportunity for an agency hearing on the record. Such order shall be treated as a final order reviewable under chapter 158 of title 28. The validity of such order may not be reviewed in an action to collect such civil penalty.

(Feb. 2, 1903, ch. 349, § 3, 32 Stat. 792; Jan. 12, 1983, Pub. L. 97–461, § 6, 96 Stat. 2525.)

REFERENCES IN TEXT

This Act, referred to in text, is act Feb. 2, 1903, ch. 349, 32 Stat. 791, as amended, which enacted sections 111, 121, and 122 of this title and amended sections 112, 113, and 120 of this title. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

1983—Pub. L. 97–461 substituted ''five thousand dollars'' for ''one thousand dollars'' and inserted provisions relating to a civil penalty.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

### § 123. Quarantine

The Secretary of Agriculture is authorized to quarantine by regulation any State or Territory or the District of Columbia, or any portion of any State or Territory or the District of Columbia, when he shall determine the fact that any animals or live poultry in such State or Territory or District of Columbia are affected with any contagious, infectious, or communicable disease of livestock or poultry or that the contagion of any such disease exists or that vectors which may disseminate any such disease exist in such State or Territory or the District of Columbia.

(Mar. 3, 1905, ch. 1496, § 1, 33 Stat. 1264; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87–518, § 8(a), 76 Stat. 131; Oct. 10, 1978, Pub. L. 95–439, § 2, 92 Stat. 1061.)

AMENDMENTS

1978—Pub. L. 95–439 struck out provision requiring the Secretary of Agriculture to give written notice of the establishment of quarantine to the proper officials of railroads, steamboats, or other transportation systems and to publish notice of the establishment of quarantine in newspapers in the quarantined State or Territory or the District of Columbia.

1962—Pub. L. 87–518 authorized quarantine upon the determination that any animals or poultry are affected with a communicable disease of livestock or poultry or that the contagion of any such disease exists or that vectors which may disseminate any such disease exist.

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock''.

SHORT TITLE

This section and sections 124 to 127 of this title are from act Mar. 3, 1905, entitled ''An act to enable the Secretary of Agriculture to establish and maintain quarantine districts, to permit and regulate the movement of cattle and other live stock therefrom, and for other purposes and constitute the Cattle Contagious Diseases Act of 1905.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 128, 136a of this title; title 16 section 1540.

### § 124. Transportation or delivery therefor from quarantined State or Territory or portion thereof, of quarantined animals and live poultry, forbidden

No railroad company or the owners or masters of any steam or sailing or other vessel or boat shall receive for transportation or transport from any quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, any quarantined animals, and/or live poultry, except as hereinafter provided; nor shall any person, company, or corporation deliver for such transportation to any railroad company, or to the master or owner of any boat or vessel, any quarantined animals and/or live poultry, except as hereinafter provided; nor shall any person, company, or corporation drive on foot, or cause to be driven on foot, or transport in private conveyance or cause to be transported in private conveyance, from a quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, and quarantined animals and/or live poultry, except as hereinafter provided.

(Mar. 3, 1905, ch. 1496, § 2, 33 Stat. 1264; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87–518, § 8(b), 76 Stat. 131.)

AMENDMENTS

1962—Pub. L. 87–518 substituted ''quarantined animals'' for ''cattle or other livestock'' wherever appearing.

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock'' wherever appearing.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 127, 128, 136a of this title; title 16 section 1540.

### § 125. Regulations for inspection, disinfection, and certification, and delivery and shipment of quarantined animals and live poultry from State or Territory

It shall be the duty of the Secretary of Agriculture, and he is authorized and directed, when the public safety will permit, to make and promulgate rules and regulations which shall permit and govern the inspection, disinfection, certification, treatment, handling, and method and manner of delivery and shipment of quarantined animals or live poultry from a quarantined State or Territory or the District of Columbia, and from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia.

(Mar. 3, 1905, ch. 1496, § 3, 33 Stat. 1265; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87–518, § 8(b), 76 Stat. 131; Oct. 10, 1978, Pub. L. 95–439, § 3, 92 Stat. 1061.)

AMENDMENTS

1978—Pub. L. 95–439 struck out provision requiring the Secretary of Agriculture to give notice of rules and regulations in the manner prescribed in section 123 of this title for notice of establishment of quarantine.

1962—Pub. L. 87–518 substituted ''quarantined animals'' for ''cattle or other livestock''.

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 126, 128, 136a of this title; title 16 section 1540.

### § 126. Moving quarantined animals and live poultry from State or Territory, under regulations

Quarantined animals and/or live poultry may be moved from a quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, under and in compliance with the rules and regulations of the Secretary of Agriculture, made and promulgated in pursuance of the provisions of section 125 of this title; but it shall be unlawful to move, or to allow to be moved, any quarantined animals and/or live poultry from any quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, in manner or method or under conditions other than those prescribed by the Secretary of Agriculture.

(Mar. 3, 1905, ch. 1496, § 4, 33 Stat. 1265; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87–518, § 8(b), 76 Stat. 131.)

AMENDMENTS

1962—Pub. L. 87–518 substituted ''quarantined animals'' for ''cattle or other livestock'' wherever appearing.

1928—Act Feb. 7, 1928, inserted ''and/or live poultry'' after ''livestock'' wherever appearing.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 127, 128, 136a of this title; title 16 section 1540.

### § 127. Transportation from quarantined State, Territory, etc.; penalty

Any person, company, or corporation violating the provisions of sections 124 or 126 of this title shall be guilty of a misdemeanor, and on conviction shall be punished by a fine of not less than one hundred dollars nor more than five thousand dollars, or by imprisonment not more than one year, or by both such fine and imprisonment. Any person, company, or corporation violating such provisions may be assessed a civil penalty by the Secretary of Agriculture of not more than one thousand dollars. The Secretary may issue an order assessing such civil penalty only after notice and an opportunity for an agency hearing on the record. Such order shall be treated as a final order reviewable under chapter 158 of title 28. The validity of such order may not be reviewed in an action to collect such civil penalty.

(Mar. 3, 1905, ch. 1496, § 6, 33 Stat. 1265; Jan. 12, 1983, Pub. L. 97–461, § 7, 96 Stat. 2525.)

AMENDMENTS

1983—Pub. L. 97–461 substituted ''five thousand dollars'' for ''one thousand dollars'' and inserted provisions relating to a civil penalty.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 128, 136a of this title; title 16 section 1540.

### § 128. Extension of quarantine law to carriers in interstate commerce

The provisions of sections 123 to 127 of this title shall apply to any railroad company or other common carrier whose road or line forms any part of a route over which quarantined animals are transported in the course of shipment from any quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia into any other State or Territory or the District of Columbia.

(June 30, 1914, ch. 131, 38 Stat. 419; July 2, 1962, Pub. L. 87–518, § 9, 76 Stat. 131.)

CODIFICATION

Section is from the Department of Agriculture Appropriation Act, 1915.

AMENDMENTS

1962—Pub. L. 87–518 substituted ''quarantined animals'' for ''cattle or other livestock''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

### §129. Expenses for arrest and eradication of contagious or infectious diseases or pests of animals, poultry, or plants

In emergencies which threaten any segment of the agricultural production industry of this country, the Secretary may transfer from other appropriations or funds available to the agencies or corporations of the Department such sums as he may deem necessary, to be available only in such emergencies for the arrest and eradication of contagious or infectious disease or pests of animals, poultry, or plants, and for expenses in accordance with sections 114b to 114d–1 of this title and section 147a of title 7, and any unexpended balances of funds transferred for such emergency purposes in the next preceding fiscal year shall be merged with such transferred amounts.

(Sept. 30, 1994, Pub. L. 103–330, title I, 108 Stat. 2443.)

CODIFICATION

Section is from the appropriation act cited as the credit to this section.

SIMILAR PROVISIONS

Similar provisions were contained in the following prior appropriation acts:
Oct. 21, 1993, Pub. L. 103–111, title I, 107 Stat. 1054.
Aug. 14, 1992, Pub. L. 102–341, title I, 106 Stat. 882.
Oct. 28, 1991, Pub. L. 102–142, title I, 105 Stat. 886.
Nov. 5, 1990, Pub. L. 101–506, title I, 104 Stat. 1323.
Nov. 21, 1989, Pub. L. 101–161, title I, 103 Stat. 959.
Oct. 1, 1988, Pub. L. 100–460, title I, 102 Stat. 2237.
Dec. 22, 1987, Pub. L. 100–202, §101(k) [title I], 101 Stat. 1329–322, 1329–331.
Oct. 18, 1986, Pub. L. 99–500, §101(a) [title I], 100 Stat. 1783, 1783–8, and Oct. 30, 1986, Pub. L. 99–591, §101(a) [title I], 100 Stat. 3341, 3341–8.
Dec. 19, 1985, Pub. L. 99–190, §101(a) [H.R. 3037, title I], 99 Stat. 1185.
Oct. 12, 1984, Pub. L. 98–473, title I, §101(a) [H.R. 5743, title I], 98 Stat. 1837.
Nov. 14, 1983, Pub. L. 98–151, §101(d) [H.R. 3223, title I], 97 Stat. 972.
Dec. 18, 1982, Pub. L. 97–370, title I, 96 Stat. 1792.
Dec. 23, 1981, Pub. L. 97–103, title I, 95 Stat. 1472.
Dec. 15, 1980, Pub. L. 96–528, title I, 94 Stat. 3099.
Nov. 9, 1979, Pub. L. 96–108, title I, 93 Stat. 826.
Oct. 11, 1978, Pub. L. 95–448, title I, 92 Stat. 1076.
Aug. 12, 1977, Pub. L. 95–97, title I, 91 Stat. 813.
July 12, 1976, Pub. L. 94–351, title I, 90 Stat. 854.
Oct. 21, 1975, Pub. L. 94–122, title I, 89 Stat. 645.
Dec. 31, 1974, Pub. L. 93–563, title I, 88 Stat. 1824.
Oct. 24, 1973, Pub. L. 93–135, title I, 87 Stat. 472.
Aug. 22, 1972, Pub. L. 92–399, title I, 86 Stat. 594.
Aug. 10, 1971, Pub. L. 92–73, title I, 85 Stat. 185.
Dec. 22, 1970, Pub. L. 91–566, title I, 84 Stat. 1482.
Nov. 26, 1969, Pub. L. 91–127, title I, 83 Stat. 246.
Aug. 8, 1968, Pub. L. 90–463, title I, 82 Stat. 640.
Oct. 24, 1967, Pub. L. 90–113, title I, 81 Stat. 321.
Sept. 7, 1966, Pub. L. 89–556, title I, 80 Stat. 690.
Nov. 2, 1965, Pub. L. 89–316, title I, 79 Stat. 1166.
Sept. 2, 1964, Pub. L. 88–573, title I, 78 Stat. 863.
Dec. 30, 1963, Pub. L. 88–250, title I, 77 Stat. 821.
Oct. 24, 1962, Pub. L. 87–879, title I, 76 Stat. 1204.
July 26, 1961, Pub. L. 87–112, title I, 75 Stat. 228.
June 29, 1960, Pub. L. 86–532, title I, 74 Stat. 233.
July 8, 1959, Pub. L. 86–80, title I, 73 Stat. 168.
June 13, 1958, Pub. L. 85–459, title I, 72 Stat. 189.
Aug. 2, 1957, Pub. L. 85–118, title I, 71 Stat. 330.
June 4, 1956, ch. 355, title I, 70 Stat. 230.
May 23, 1955, ch. 43, title I, 69 Stat. 52.
June 29, 1954, ch. 409, title I, 68 Stat. 305.
July 28, 1953, ch. 251, title III, 67 Stat. 223.
July 5, 1952, ch. 574, title III, 66 Stat. 354.
Aug. 31, 1951, ch. 374, title II, 65 Stat. 243.
Sept. 6, 1950, ch. 896, Ch. VI, title I, 64 Stat. 661.
June 29, 1949, ch. 280, title I, 63 Stat. 332.
June 19, 1948, ch. 543, 62 Stat. 515.
July 30, 1947, ch. 356, title I, 61 Stat. 532.
June 22, 1946, ch. 445, 60 Stat. 278.
May 5, 1945, ch. 109, 59 Stat. 144.
June 28, 1944, ch. 296, 58 Stat. 434.
July 12, 1943, ch. 215, 57 Stat. 403.
July 22, 1942, ch. 516, 56 Stat. 676.
July 1, 1941, ch. 267, 55 Stat. 418.
June 25, 1940, ch. 421, 54 Stat. 542.
June 30, 1939, ch. 253, title I, 53 Stat. 951.
June 16, 1938, ch. 464, title I, 52 Stat. 722.
June 29, 1937, ch. 404, 50 Stat. 406.
June 4, 1936, ch. 489, 49 Stat. 1432.
May 17, 1935, ch. 131, title I, 49 Stat. 257.
Mar. 26, 1934, ch. 89, 48 Stat. 477.
Mar. 3, 1933, ch. 203, 47 Stat. 1442.
July 7, 1932, ch. 443, 47 Stat. 620.
Feb. 23, 1931, ch. 278, 46 Stat. 1252.
May 27, 1930, ch. 341, 46 Stat. 403.
Feb. 16, 1929, ch. 227, 45 Stat. 1198.
May 16, 1928, ch. 572, 45 Stat. 548.
Jan. 18, 1927, ch. 39, 44 Stat. 1005.
May 11, 1926, ch. 286, 44 Stat. 529.
Feb. 10, 1925, ch. 200, 43 Stat. 851.
Dec. 5, 1924, ch. 4, 43 Stat. 683.
June 5, 1924, ch. 266, 43 Stat. 458.
Apr. 2, 1924, ch. 81, 43 Stat. 40.
Feb. 26, 1923, ch. 119, 42 Stat. 1318.
May 11, 1922, ch. 185, 42 Stat. 536.
Mar. 4, 1917, ch. 179, 39 Stat. 1167.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

### §130. Pleuropneumonia in District of Columbia; duties of Council of the District of Columbia

Whenever any contagious, infectious, or communicable disease affecting domestic animals or live poultry, and especially the disease known as pleuropneumonia, shall be brought into or shall break out in the District of Columbia, it shall be the duty of the Council of the District of Columbia to take measures to suppress the same promptly and to prevent the same from spreading; and for this purpose the said Council is empowered to order and require that any premises, farm, or farms where such disease exists, or has existed, be put in quarantine; to order all or any animals coming into the District to be detained at any place or places for the purpose of inspection and examination; to prescribe regulations for and to require the destruction of animals or live poultry affected with contagious, infectious, or communicable disease, and for the proper disposition of their hides and carcasses; to prescribe regulations for disinfection, and such other regulations as they may deem necessary to prevent infection or contagion being communicated, and shall report to the Secretary of Agriculture whatever it may do in pursuance of the provisions of this section.

(May 29, 1884, ch. 60, §8, 23 Stat. 33; 1967 Reorg. Plan No. 3, §402(430), eff. Aug. 11, 1967, 32 F.R. 11669, 81 Stat. 948; Pub. L. 93–198, title IV, §401, Dec. 24, 1973, 87 Stat. 793.)

CODIFICATION

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see note set out under section 112 of this title.

Section is also set out in D.C. Code § 1–324.

TRANSFER OF FUNCTIONS

''Council of the District of Columbia'' substituted in text for ''District of Columbia Council'' pursuant to section 401 of Pub. L. 93–198. District of Columbia Council, as established by Reorg. Plan No. 3 of 1967, abolished as of noon Jan. 2, 1975, by Pub. L. 93–198, title VII, § 711, Dec. 24, 1973, 87 Stat. 818, classified to section 1–211 of the District of Columbia Code, and replaced by Council of the District of Columbia, as provided by section 401 of Pub. L. 93–198, classified to section 1–221 of the District of Columbia Code.

Previously, references to Commissioners of District of Columbia had been changed to District of Columbia Council pursuant to section 402(430) of Reorganization Plan No. 3 of 1967, 32 F.R. 11669, effective Aug. 11, 1967, set out in the Appendix to Title 5, Government Organization and Employees, which transferred regulatory and other functions of Board of Commissioners relating to prescribing of regulations for destruction of animals or live poultry affected by contagious, infectious, or communicable disease, and for proper disposition of their hides and carcasses, and prescribing of regulations for disinfection and other regulations under this section to District of Columbia Council, subject to right of Commissioner as provided by section 406 of Plan. For provisions establishing District of Columbia Council, see section 201 of Reorg. Plan No. 3 of 1967.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

CROSS REFERENCES

Diseases and quarantine in the District of Columbia, see sections 111 and 123 to 127 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119, 136a of this title; title 16 section 1540.

### § 131. Fences along international boundary lines to keep out diseased animals

The Secretary of Agriculture may permit the erection of fences along international boundary lines, but entirely within the territory of the United States, for the purpose of keeping out diseased animals.

(May 26, 1910, ch. 256, 36 Stat. 440.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 136a of this title; title 16 section 1540.

### § 132. Transferred

CODIFICATION

Section, act May 23, 1908, ch. 192, 35 Stat. 254, which related to inspection of dairy products for export, was transferred to section 693 of this title.

### § 133. Repealed. July 13, 1949, ch. 307, 63 Stat. 410

Section, act July 24, 1946, ch. 592, 60 Stat. 633, related to establishment of a quarantine station on Swan Island.

### § 134. Definitions

As used in this Act unless the context indicates otherwise—

(a) The term ''Secretary'' means the Secretary of Agriculture.

(b) The term ''animals'' means all members of the animal kingdom including birds, whether domesticated or wild, but not including man.

(c) The term ''United States'' means the States, Puerto Rico, Guam, the Virgin Islands of the United States, and the District of Columbia.

(d) The term ''interstate'' means from a State or other area included in the definition of ''United States'' to or through any other State or other such area.

(Pub. L. 87–518, § 1, July 2, 1962, 76 Stat. 129.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87–518, July 2, 1962, 76 Stat. 129, as amended, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18, Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134e, 134f, 134g, 134h, 136a of this title; title 16 section 1540.

### § 134a. Seizure, quarantine, and disposal of livestock or poultry to guard against introduction or dissemination of communicable disease

#### (a) Authority of Secretary

The Secretary, whenever he deems it necessary in order to guard against the introduction or dissemination of a communicable disease of livestock or poultry, may seize, quarantine, and dispose of, in a reasonable manner taking into consideration the nature of the disease and the necessity of such action to protect the livestock or poultry of the United States: (1) any animals which he finds are moving or are being handled or have moved or have been handled in interstate or foreign commerce contrary to any law or regulation administered by him for the prevention of the introduction or dissemination of any communicable disease of livestock or poultry; (2) any animals which he finds are moving into the United States, or interstate, and are affected with or have been exposed to any communicable disease dangerous to livestock or poultry; and (3) any animals which he finds have moved into the United States, or interstate, and at the time of such movement were so affected or exposed.

#### (b) Determination of extraordinary emergency due to dangerous communicable disease; seizure, quarantine, and disposal of animals; action authorized only if adequate measures not taken by State or other jurisdiction; notice to State or other jurisdiction

Whereas the existence of any dangerous, communicable disease of livestock or poultry, such as foot-and-mouth disease, rinderpest, or European fowl pest, on any premises in the United States would constitute a threat to livestock and poultry of the Nation and would seriously burden interstate and foreign commerce, whenever the Secretary determines that an extraordinary emergency exists because of the outbreak of such a disease anywhere in the United States, and that such outbreak threatens the livestock or poultry of the United States, he may seize, quarantine, and dispose of, in such manner as he deems necessary or appropriate, any animals in the United States which he finds are or have been affected with or exposed to any such dis-

ease and the carcasses of any such animals and any products and articles which he finds were so related to such animals as to be likely to be a means of disseminating any such disease: *Provided,* That action shall be taken under this subsection only if the Secretary finds that adequate measures are not being taken by the State or other jurisdiction. The Secretary shall notify the appropriate official of the State or other jurisdiction before any action is taken in any such State or other jurisdiction pursuant to this subsection.

**(c) Notice to owner to quarantine or to dispose of animal, carcass, product, or article; action on failure to comply; costs**

The Secretary in writing may order the owner of any animal, carcass, product, or article referred to in subsection (a) or (b) of this section, or the agent of such owner, to maintain in quarantine, and to dispose of such animal, carcass, product, or article in such manner as the Secretary may direct pursuant to authority vested in him by such subsections. If such owner or agent fails to do so after receipt of such notice, the Secretary may take action as authorized by said subsections (a) and (b) and recover from such owner or agent the reasonable costs of any care, handling, and disposal incurred by the Secretary in connection therewith. Such costs shall not constitute a lien against the animals, carcasses, products, or articles involved. Costs collected under this section shall be credited to the current appropriation for carrying out animal disease control activities of the Department.

**(d) Compensation of owner; fair market value; payments from State or other source; availability of funds**

Except as provided in subsection (e) of this section, the Secretary shall compensate the owner of any animal, carcass, product, or article destroyed pursuant to the provisions of this section. Such compensation shall be based upon the fair market value as determined by the Secretary, of any such animal, carcass, product, or article at the time of the destruction thereof. Compensation paid any owner under this subsection shall not exceed the difference between any compensation received by such owner from a State or other source and such fair market value of the animal, carcass, product, or article. Funds in the Treasury available for carrying out animal disease control activities of the Department of Agriculture shall be used for carrying out this subsection.

**(e) Restriction on payment of compensation in cases of violation of law or regulation**

No such payment shall be made by the Secretary for any animal, carcass, product, or article which has been moved or handled by the owner thereof or his agent knowingly in violation of a law or regulation administered by the Secretary for the prevention of the interstate dissemination of the communicable disease, for which the animal, carcass, product, or article was destroyed or a law or regulation for the enforcement of which the Secretary enters or has entered into a cooperative agreement for the control and eradication of such disease, or for any animal which has moved into the United States contrary to such law or regulation administered by the Secretary for the prevention of the introduction of a communicable disease of livestock or poultry.

(Pub. L. 87–518, § 2, July 2, 1962, 76 Stat. 129.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h, 136a of this title; title 16 section 1540.

### § 134b. Regulations for clean and sanitary movement of animals

The Secretary, in order to protect the health of the livestock or poultry of the Nation, may promulgate regulations requiring that railway cars; vessels; airplanes; trucks; and other means of conveyance; stockyards; feed, water, and rest stations; and other facilities, used in connection with the movement of animals into or from the United States, or interstate, be maintained in a clean and sanitary condition, including requirements for inspection, cleaning, and disinfection.

(Pub. L. 87–518, § 3, July 2, 1962, 76 Stat. 130.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h, 136a of this title; title 16 section 1540.

### § 134c. Regulations for movement of animals affected or exposed to communicable disease

The Secretary is authorized to promulgate regulations prohibiting or regulating the movement into the United States of any animals which are or have been affected with or exposed to any communicable animal disease, or which have been vaccinated or otherwise treated for any such disease, or which he finds would otherwise be likely to introduce or disseminate any such disease, when he determines that such action is necessary to protect the livestock or poultry of the United States.

(Pub. L. 87–518, § 4, July 2, 1962, 76 Stat. 130.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h, 136a of this title; title 16 section 1540.

### § 134d. Inspections and seizures; issuance of warrants

Employees of the Department of Agriculture designated by the Secretary for the purpose, when properly identified, shall have authority (1) to stop and inspect, without a warrant, any person or means of conveyance, moving into the United States from a foreign country, to determine whether such person or means of conveyance is carrying any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for prevention of the introduction or dissemination of any communicable animal disease; (2) to stop and inspect, without a warrant, any means of conveyance moving interstate upon probable cause to believe that such means of conveyance is carrying any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any communicable

animal disease; and (3) to enter upon, with a warrant, any premises for the purpose of making inspections and seizures necessary under such laws and regulations. Any Federal judge, or any judge of a court of record in the United States, or any United States magistrate judge, may, within his jurisdiction, upon proper oath or affirmation indicating probable cause to believe that there is on certain premises any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any communicable animal disease, issue warrants for the entry upon such premises and for inspections and seizures necessary under such laws and regulations. Such warrants may be executed by any authorized employee of the Department of Agriculture.

(Pub. L. 87–518, § 5, July 2, 1962, 76 Stat. 130; Pub. L. 90–578, title IV, § 402(b)(2), Oct. 17, 1968, 82 Stat. 1118; Pub. L. 101–650, title III, § 321, Dec. 1, 1990, 104 Stat. 5117.)

CHANGE OF NAME

''United States magistrate judge'' substituted in text for ''United States magistrate'' pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure. Previously, ''United States magistrate'' substituted for ''United States commissioner'' pursuant to Pub. L. 90–578. See chapter 43 (§ 631 et seq.) of Title 28.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h, 136a of this title; title 16 section 1540.

### § 134e. Enforcement provisions

#### (a) Criminal and civil penalties

(1) Whoever knowingly violates any regulation promulgated pursuant to the provisions of sections 134 through 134d of this title shall be punished by a fine not exceeding $5,000 or by imprisonment not exceeding one year, or both.

(2) Whoever violates any such regulation may be assessed a civil penalty by the Secretary not exceeding $1,000. The Secretary may issue an order assessing such civil penalty only after notice and an opportunity for an agency hearing on the record. Such order shall be treated as a final order reviewable under chapter 158 of title 28. The validity of such order may not be reviewed in an action to collect such civil penalty.

#### (b) Injunctive proceedings

The Secretary may bring an action to enjoin the violation of, or to compel compliance with, any regulation promulgated or order issued under said sections, or to enjoin any interference by any person with an employee of the Department of Agriculture in carrying out any duties under said sections, whenever the Secretary has reason to believe that such person has violated, or is about to violate, any such regulation or order, or has interfered, or is about to interfere, with any such employee. Such action shall be brought in the United States district court, or the United States court of any Territory or possession, for the judicial district in which such person resides or transacts business or in which the violation, omission, or interference has occurred or is about to occur. Process in such cases may be served in any judicial district wherein the defendant resides or transacts business or wherever the defendant may be found, and subpenas for witnesses who are required to attend the court in any judicial district in any such cases may run into any other judicial district.

(Pub. L. 87–518, § 6, July 2, 1962, 76 Stat. 131; Pub. L. 97–461, § 8, Jan. 12, 1983, 96 Stat. 2525.)

AMENDMENTS

1983—Subsec. (a). Pub. L. 97–461 designated existing provisions as par. (1), substituted ''$5,000'' for ''$1,000'', and added par. (2).

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134f, 134g, 134h, 136a of this title; title 16 section 1540.

### § 134f. Promulgation of regulations

The Secretary is authorized to issue such regulations as he deems necessary to carry out the provisions of this Act.

(Pub. L. 87–518, § 11, July 2, 1962, 76 Stat. 132.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87–518, July 2, 1962, 76 Stat. 129, as amended, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18, Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134g, 134h, 136a of this title; title 16 section 1540.

### § 134g. Authority in addition to other laws; repeal of inconsistent provisions

The authority conferred by this Act shall be in addition to authority conferred by other statutes. Any provision of any other Act inconsistent with the provisions of this Act is repealed.

(Pub. L. 87–518, § 12, July 2, 1962, 76 Stat. 132.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87–518, July 2, 1962, 76 Stat. 129, as amended, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18, Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134f, 134h, 136a of this title; title 16 section 1540.

### § 134h. Separability

If any provision of this Act or application thereof to any person or circumstances is held invalid, the remainder of the Act and the application of such provision to other persons and circumstances shall not be affected thereby.

(Pub. L. 87–518, § 13, July 2, 1962, 76 Stat. 132.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87–518, July 2, 1962, 76 Stat. 129, as amended, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18,

Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134f, 134g, 136a of this title; title 16 section 1540.

### § 135. International animal quarantine station; establishment; acceptance of gifts; cooperation with breeders' organizations; collection of fees

The Secretary of Agriculture is authorized, in his discretion, to establish and maintain an international animal quarantine station within the territory of the United States. The quarantine station shall be located on an island selected by the Secretary of Agriculture where, in his judgment, maximum animal disease and pest security measures can be maintained. The Secretary of Agriculture is authorized to acquire land or any interest therein, by purchase, donation, exchange, or otherwise and construct or lease buildings, improvements, and other facilities as may be necessary for the establishment and maintenance of such quarantine station. The Secretary of Agriculture, on behalf of the United States, is authorized to accept any gift or donation of money, personal property, buildings, improvements, and other facilities for the purpose of conducting the functions authorized under sections 135 to 135b of this title. Notwithstanding the provisions of any other law to prevent the introduction or dissemination of livestock or poultry disease or pests, animals may be brought into the quarantine station from any country, including but not limited to those countries in which the Secretary of Agriculture determines that rinderpest or foot-and-mouth disease exists, and subsequently moved into other parts of the United States in accordance with such conditions as the Secretary of Agriculture shall determine are adequate in order to prevent the introduction into and the dissemination within the United States of livestock or poultry diseases or pests. The Secretary of Agriculture is authorized to cooperate in such manner as he deems appropriate, with other countries or with breeders' organizations or similar organizations or with individuals regarding importation of animals into and through the quarantine station and to charge and collect reasonable fees for use of the facilities of such station from importers. Such fees shall be deposited into the Treasury of the United States to the credit of the appropriation charged with the operating expenses of the quarantine station. The Secretary is authorized to issue such regulations as he deems necessary to carry out the provisions of sections 135 to 135b of this title.

(Pub. L. 91–239, § 1, May 6, 1970, 84 Stat. 202; Pub. L. 103–465, title IV, § 431(j), Dec. 8, 1994, 108 Stat. 4969.)

AMENDMENTS

1994—Pub. L. 103–465, in sixth sentence, struck out ''North American'' before ''countries'' and ''within the United States'' after ''individuals''.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective, except as otherwise provided, on the date of entry into force of the World Trade Organization Agreement with respect to the United States [Jan. 1, 1995], see section 451 of Pub. L. 103–465, set out as an Effective Date note under section 3601 of Title 19, Customs Duties.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 135a, 135b, 136a of this title; title 16 section 1540.

### § 135a. Smuggling penalties

**(a) Criminal penalty**

The provisions and penalties of section 545 of title 18 shall apply to the bringing of animals to the quarantine station or the subsequent movement of animals to other parts of the United States, including Puerto Rico, Guam, and the Virgin Islands, contrary to the conditions prescribed by the Secretary in regulations issued hereunder.

**(b) Civil penalty**

Any person who brings any animal to the quarantine station or moves any animal from the quarantine station, contrary to the conditions prescribed by the Secretary in regulations issued hereunder, may be assessed a civil penalty by the Secretary not to exceed $1,000. The Secretary may issue an order assessing such civil penalty only after notice and an opportunity for an agency hearing on the record. Such order shall be treated as a final order reviewable under chapter 158 of title 28. The validity of such order may not be reviewed in an action to collect such civil penalty.

(Pub. L. 91–239, § 2, May 6, 1970, 84 Stat. 202; Pub. L. 97–461, § 9, Jan. 12, 1983, 96 Stat. 2525.)

AMENDMENTS

1983—Pub. L. 97–461 designated existing provisions as subsec. (a) and added subsec. (b).

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 135, 135b of this title; title 16 section 1540.

### § 135b. Authorization of appropriations

There are hereby authorized to be appropriated such sums as are necessary to carry out the provisions of sections 135 to 135b of this title.

(Pub. L. 91–239, § 3, May 6, 1970, 84 Stat. 202.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 135, 135a of this title; title 16 section 1540.

### § 136. Additional inspection services

The Secretary of Agriculture, in carrying out regulations prohibiting or restricting the entry of materials that may harbor pests, or diseases, is authorized to enter into agreements with operators or owners of vessels or aircraft for the purpose of providing inspection services at points of entry in the United States in addition to the regular or on-call basis currently available in connection with such vessels or aircraft. Any such agreement shall provide for the payment by the operator or owner of an amount determined by the Secretary to be necessary to defray the costs of providing additional service pursuant to such agreement.

(Pub. L. 101–624, title XXV, § 2508, Nov. 28, 1990, 104 Stat. 4069.)

**§ 136a. Collection of fees for inspection services**

**(a) Quarantine, inspection and transportation fees**

**(1) Quarantine and inspection**

**(A) In general**

The Secretary of Agriculture (hereafter referred to in this section as the ''Secretary'') may prescribe and collect fees to cover the cost of providing agricultural quarantine and inspection services in connection with the arrival at a port in the customs territory of the United States, or the preclearance or preinspection at a site outside the customs territory of the United States, of an international passenger, commercial vessel, commercial aircraft, commercial truck, or railroad car.

**(B) Airport inspection services**

For airport inspection services, the Secretary shall collect no more than $69,000,000 in fiscal year 1992 and $75,000,000 in fiscal year 1993 from international airline passengers and commercial aircraft operators.

**(C) Commercial truck and railroad car inspection services**

For commercial truck and railroad car inspection services, the Secretary shall collect no more than $3,667,000 in fiscal year 1992 and $3,890,000 in fiscal year 1993 from commercial truck and railroad car operators.

**(D) Costs**

Fees, including fees from international airline passengers and commercial aircraft operators, may only be collected to the extent that the Secretary reasonably estimates that the amount of the fees are commensurate with the costs of agricultural quarantine and inspection services with respect to the class of persons or entities paying the fees. The costs of such services with respect to passengers as a class includes the costs of related inspections of the aircraft.

**(2) Treasury**

Any person who collects a fee under this subsection shall remit such fee to the Treasury of the United States prior to the date that is 31 days after the close of the calendar quarter in which such fee is collected.

**(3) Agricultural Quarantine Inspection User Fee Account**

**(A) Establishment**

There is established in the Treasury of the United States a no-year fund, to be known as the ''Agricultural Quarantine Inspection User Fee Account'' (hereafter referred to in this section as the ''Account''), for the use of the Secretary for quarantine or inspection services under this section.

**(B) Amounts in Account**

**(i) Deposits**

All of the fees collected under this subsection shall be deposited in the Account.

**(ii) Reimbursement**

The Secretary of the Treasury shall use the Account to provide reimbursements to any appropriation accounts that incur the costs associated with the administration of this subsection and all other activities carried out by the Secretary at ports in the customs territory of the United States and at preclearance or preinspection sites outside the customs territory of the United States in connection with the enforcement of the animal quarantine laws. Any such reimbursement shall be subject to appropriations under clause (v).

**(iii) Procedure**

The Secretary of the Treasury shall make reimbursement under clause (ii) on a quarterly basis. Amounts required to be reimbursed under clause (ii), shall be made on the basis of estimates made by the Secretary of the expenses described in clause (ii) that are incurred by the Secretary in the 3-month period immediately preceding such reimbursement.

**(iv) Adjustments**

Adjustments of reimbursements made under clause (ii) shall be made to the extent necessary to correct prior estimates that were in excess of, or less than, the amount required to be reimbursed under clause (iii).

**(v) Authorization of appropriations**

There are authorized to be appropriated each fiscal year amounts in the Fund[1] for use for quarantine or inspection services.

**(4) Adjustment in fee amounts**

Subject to the limits set forth in paragraph (1), the Secretary shall adjust the amount of the fees to be assessed under this subsection to reflect the cost to the Secretary in administering such subsection, in carrying out the activities at ports in customs territory of the United States and preclearance and preinspection sites outside the customs territory of the United States in connection with the provision of agricultural quarantine inspection services, and in maintaining a reasonable balance in the Account.

**(b) Omitted**

**(c) Animal inspection and veterinary diagnostics**

**(1) Animal inspection**

The Secretary may prescribe and collect fees to reimburse the Secretary for the cost of carrying out the provisions of the Federal Animal Quarantine Laws that relate to the importation, entry, and exportation of animals, articles, or means of conveyance.

**(2) Omitted**

**(3) Fees**

All fees collected pursuant to this subsection and any late payment penalties or accrued interest collected pursuant to this subsection shall be credited to the accounts that

[1] So in original. Probably should be ''Account''.

incur the cost and shall remain available until expended without fiscal year limitation.

**(4) Liability**

Any person for whom an activity related to the importation, entry, or exportation of an animal, article, or means of conveyance or relating to veterinary diagnostics, is performed pursuant to the section, shall be liable for payment of fees assessed. Upon failure to pay such fees when due, the Secretary shall assess a late payment penalty, and such overdue fees shall accrue interest, as required by section 3717 of title 31. All fees, late payment penalties, and accrued interest collected shall be credited to such accounts that incur the costs and shall remain available until expended without fiscal year limitation.

**(5) Leins**[2]

**(A) In general**

The Secretary shall have a lien against the animal, article, means of conveyance, or facility for which services have been provided under this section for the fees, any late payment penalty, and any accrued interest assessed under this subsection.

**(B) Other animals, etc.**

In the case of any person who fails to make payment when due under this subsection, the Secretary shall have a lien against any animal, article, or means of conveyance thereafter imported, moved in interstate commerce, or attempted to be exported by the person after the date of such failure until the date on which such owner or operator make[3] full payment to the Secretary under this subsection.

**(C) Sales of animals, etc.**

**(i) Authority**

The Secretary may, if a person does not pay fees, late payment penalties, or accrued interest on such, after providing reasonable notice of default to such person, sell at public sale after reasonable public notice, or otherwise dispose of, any such animal, article, means of conveyance or facility on which the Secretary has a lien under this paragraph.

**(ii) Excess proceeds**

If the sale proceeds under clause (i) exceed the fees due, any late payment penalty assessed, any accrued interest on such, and the expenses associated with the sale, such excess shall be paid to the owner of the animal, article, means of conveyance, or facility if such owner submits an application for such excess together with proof of ownership not later than 6 months after the date of such sale. If no such application is made, such excess shall be credited to accounts that incur the costs associated with the fees collected and shall remain available until expended, without fiscal year limitation. The Secretary shall suspend performance of services to persons who have failed to pay fees, late payment penalty, or accrued interest under this section.

**(d) Regulations**

The Secretary may prescribe such regulations as the Secretary determines necessary to carry out the provisions of this section.

**(e) Recovery of amounts owed**

An action may be brought for the recovery of fees, late payment penalties, and accrued interest which have not been paid in accordance with this section against any person obligated for payment of such assessments under this section in any United States district court or other United States court for any territory or possession in any jurisdiction in which such person is found or resides or transacts business, and such court shall have jurisdiction to hear and decide such action.

**(f) Definitions**

**(1) Animal quarantine laws**

For purposes of this section, the term ''animal quarantine laws'' means—

(A) section 306 of the Tariff Act of 1930 (19 U.S.C. 1306);

(B) sections 6 through 10 of the Act of August 30, 1890 (26 Stat. 416, chapter 839; 21 U.S.C. 101–105);

(C) section 2 of the Act of February 2, 1903 (32 Stat. 792, chapter 349; 21 U.S.C. 111);

(D) the Act of May 29, 1884 (23 Stat. 32, chapter 60; 21 U.S.C. 112 to 114a–1, 115, 117–119, and 130) (commonly known as the ''Animal Industry Act'');

(E) the Act of February 28, 1947 (61 Stat. 7, chapter 8; 21 U.S.C. 114b, 114c, and 114d–1);

(F) the Act of June 16, 1948 (62 Stat. 458, chapter 477; 21 U.S.C. 114e and 114f);

(G) Public Law 87–209 (21 U.S.C. 114g and 114h);

(H) the Act of May 31, 1920 (41 Stat. 699, chapter 217; 21 U.S.C. 116);

(I) the Act of February 2, 1903 (32 Stat. 791, chapter 349; 21 U.S.C. 112 and 120–122) (commonly known as the ''Cattle Contagious Diseases Act of 1903'');

(J) the Act of March 3, 1905 (33 Stat. 1264, chapter 1496; 21 U.S.C. 123–127) (commonly known as the ''Cattle Contagious Diseases Act of 1905'');

(K) the matter under the heading ''Bureau of Animal Industry'' of the Act of June 30, 1914 (38 Stat. 419, chapter 131; 21 U.S.C. 128);

(L) section 101 of Public Law 92–73 (21 U.S.C. 129);

(M) the matter under the heading ''Miscellaneous'' of the Act of May 26, 1910 (36 Stat. 440, chapter 256; 21 U.S.C. 131);

(N) sections 1 through 6 and 11 through 13 of Public Law 87–518 (21 U.S.C. 134–134h); or

(O) any other Act administered by the Secretary relating to plant or animal diseases or pests, other than the first section of Public Law 91–239 (21 U.S.C. 135).

**(2) Customs territory**

For the purposes of subsection (a) of this section, the term ''customs territory of the United States'' means the 50 States, the District of Columbia, and Puerto Rico.

[2] So in original. Probably should be ''Liens''.

[3] So in original. Probably should be ''makes''.

**(3) Person**

For the purposes of this section, the term ''person'' means an individual, corporation, partnership, trust, association, or any other public or private entity, or any officer, employee, or agent thereof.

**(4) United States**

For the purposes of subsection (b) of this section, the term ''United States'' means the several States of the United States, the District of Columbia, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

**(5) Vessel**

For the purposes of subsection (a) of this section, the term ''vessel'' does not include any ferry.

(Pub. L. 101–624, title XXV, § 2509, Nov. 28, 1990, 104 Stat. 4069; Pub. L. 101–508, title I, § 1203, Nov. 5, 1990, 104 Stat. 1388–11; Pub. L. 102–237, title X, § 1015, Dec. 13, 1991, 105 Stat. 1902.)

REFERENCES IN TEXT

Section 101 of Public Law 92–73, referred to in subsec. (f)(1)(L), is listed in a Similar Provisions note set out under section 129 of this title.

CODIFICATION

Section is comprised of section 2509 of Pub. L. 101–624. Subsecs. (b) and (c)(2) of section 2509 of Pub. L. 101–624 amended section 147a(f) of Title 7, Agriculture, and section 114a of this title, respectively.

AMENDMENTS

1991—Subsec. (a)(1). Pub. L. 102–237, § 1015(1), designated existing provisions as subpar. (A), realigned margin, added heading, and added subpars. (B) to (D).

Subsec. (a)(3)(B)(ii). Pub. L. 102–237, § 1015(2), added cl. (ii) and struck out former cl. (ii) which read as follows: ''The Secretary of Treasury shall use the Account to provide reimbursements to any appropriations accounts that incur the costs associated with the services authorized in paragraph (1). Any such reimbursement shall be subject to appropriations under clause (v).''

Subsec. (a)(4). Pub. L. 102–237, § 1015(3), substituted ''Subject to the limits set forth in paragraph (1), the'' for ''The''.

1990—Subsec. (a)(1). Pub. L. 101–508, § 1203(1), substituted ''an international passenger, commercial vessel, commercial aircraft, commercial truck, or railroad car.'' for ''a commercial vessel, commercial aircraft, commercial truck, or railroad car,''.

Subsec. (a)(3)(B)(ii). Pub. L. 101–508, § 1203(2)(A), inserted at end ''Any such reimbursement shall be subject to appropriations under clause (v).''

Subsec. (a)(3)(B)(v). Pub. L. 101–508, § 1203(2)(B), added cl. (v).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–508 effective Nov. 29, 1990, see section 1301 of Pub. L. 101–508, set out as a note under section 511r of Title 7, Agriculture.

## SUBCHAPTER IV—IMPORTATION OF MILK AND CREAM

FEDERAL FOOD, DRUG, AND COSMETIC ACT

By virtue of act June 25, 1938, ch. 675, § 902(c), 52 Stat. 1059 [section 392(b) of this title], nothing contained in section 301 et seq. of this title shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of this subchapter.

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 392 of this title.

### § 141. Prohibition of importation without permit

On and after May 16, 1927, the importation into the United States of milk and cream is prohibited unless the person by whom such milk or cream is shipped or transported into the United States holds a valid permit from the Secretary of Health and Human Services.

(Feb. 15, 1927, ch. 155, § 1, 44 Stat. 1101; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

SHORT TITLE

Act July 12, 1943, ch. 221, title II, 57 Stat. 499, provided in part that act Feb. 15, 1927, which is classified to this subchapter, may be cited as ''Import Milk Act''.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see note set out under section 41 of this title.

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act as not affecting, modifying, repealing, or superseding this subchapter, see section 392 of this title.

### § 142. Milk or cream when unfit for importation

Milk or cream shall be considered unfit for importation (1) when all cows producing such milk or cream are not healthy and a physical examination of all such cows has not been made within one year previous to such milk being offered for importation; (2) when such milk or cream, if raw, is not produced from cows which have passed a tuberculin test applied by a duly authorized official veterinarian of the United States, or of the country in which such milk or cream is produced, within one year previous to the time of the importation, showing that such cows are free from tuberculosis; (3) when the sanitary conditions of the dairy farm or plant in which such milk or cream is produced or handled do not score at least fifty points out of one hundred points according to the methods for scoring as provided by the score cards, used by the Bureau of Dairy Industry of the United States Department of Agriculture at the time such dairy farms or plants are scored; (4) in the case of raw milk if the number of bacteria per cubic centimeter exceeds three hundred thousand and in the case of raw cream seven hundred and fifty thousand, in the case of pasteurized milk if the number of bacteria per cubic centimeter exceeds one hundred thousand, and in the case of pasteurized cream five hundred thousand; (5) when the temperature of milk or cream at the time of importation exceeds fifty degrees Fahrenheit.

(Feb. 15, 1927, ch. 155, § 2, 44 Stat. 1101.)

TRANSFER OF FUNCTIONS

Agricultural Research Service became the successor to functions of Bureau of Dairy Industry under Secretary of Agriculture's Memorandum 1320, Supplement 4, Nov. 2, 1953.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 143 of this title.

### § 143. Inspection; certified statement in lieu thereof; waiver of requirements of section 142; regulations; suspension and revocation of permits

The Secretary of Health and Human Services shall cause such inspections to be made as are necessary to insure that milk and cream are so produced and handled as to comply with the provisions of section 142 of this title, and in all cases when he finds that such milk and/or cream is produced and handled so as not to be unfit for importation under clauses 1, 2, and 3 of section 142 of this title, he shall issue to persons making application therefor permits to ship milk and/or cream into the United States: *Provided*, That in lieu of the inspections to be made by or under the direction of the Secretary he may, in his discretion, accept a duly certified statement signed by a duly accredited official of an authorized department of any foreign government and/or of any State of the United States or any municipality thereof that the provisions in clauses 1, 2, and 3 of section 142 of this title have been complied with. Such certificate of the accredited official of an authorized department of any foreign government shall be in the form prescribed by the Secretary, who is authorized and directed to prescribe such form as well as rules and regulations regulating the issuance of permits to import milk or cream into the United States.

The Secretary is authorized, in his discretion, to waive the requirement of clause 4 of section 142 of this title when issuing permits to operators of condenseries in which milk and/or cream is used when sterilization of the milk and/or cream is a necessary process: *Provided*, *however*, That no milk and/or cream shall be imported whose bacterial count per cubic centimeter in any event exceeds one million two hundred thousand: *Provided*, *further*, That such requirements shall not be waived unless the farm producing such milk to be imported is within a radius of fifteen miles of the condensery in which it is to be processed: *Provided further*, That if milk and/or cream imported when the requirements of clause 4 of section 142 of this title, have been so waived, is sold, used, or disposed of in its raw state or otherwise than as condensed milk by any person, the permit shall be revoked and the importer shall be subject to fine, imprisonment, or other penalty prescribed by this subchapter.

The Secretary is directed to waive the requirements of clauses 2 and 5 of section 142 of this title insofar as the same relate to milk when issuing permits to operators of, or to producers for delivery to, creameries and condensing plants in the United States within twenty miles of the point of production of the milk, and who import no raw milk except for pasteurization or condensing: *Provided*, That if milk imported when the requirements of clauses 2 and 5 of section 142 of this title have been so waived is sold, used, or disposed of in its raw state, or otherwise than as pasteurized, condensed, or evaporated milk by any person, the permit shall be revoked and the importer shall be subjected to fine, imprisonment, or other penalty prescribed by this subchapter.

The Secretary is authorized and directed to make and enforce such regulations as may in his judgment be necessary to carry out the purpose of this subchapter for the handling of milk and cream, for the inspection of milk, cream, cows, barns, and other facilities used in the production and handling of milk and/or cream and the handling, keeping, transporting, and importing of milk and/or cream: *Provided*, *however*, That unless and until the Secretary shall provide for inspections to ascertain that clauses 1, 2, and 3 of section 142 of this title have been complied with, the Secretary shall issue temporary permits to any applicants therefor to ship or transport milk and/or cream into the United States.

The Secretary is authorized to suspend or revoke any permit for the shipment of milk or cream into the United States when he shall find that the holder thereof has failed to comply with the provisions of or has violated this subchapter or any of the regulations made hereunder, or that the milk and/or cream brought or shipped by the holder of such permit into the United States is not produced and handled in conformity with, or that the quality thereof does not conform to, all of the provisions of section 142 of this title.

(Feb. 15, 1927, ch. 155, § 3, 44 Stat. 1102; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see note set out under section 41 of this title.

### § 144. Unlawful receiving of imported milk or cream

It shall be unlawful for any person in the United States to receive milk or cream imported into the United States unless the importation is in accordance with the provisions of this subchapter.

(Feb. 15, 1927, ch. 155, § 4, 44 Stat. 1103.)

### § 145. Penalties

Any person who knowingly violates any provision of this subchapter shall, in addition to all other penalties prescribed by law, be punished by a fine of not less than $50 nor more than $2,000, or by imprisonment for not more than

one year, or by both such fine and imprisonment.

(Feb. 15, 1927, ch. 155, § 5, 44 Stat. 1103.)

### § 146. Authorization of appropriations

There is authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, the sum of $50,000 per annum, to enable the Secretary of Health and Human Services to carry out the provisions of this subchapter.

(Feb. 15, 1927, ch. 155, § 6, 44 Stat. 1103; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

### § 147. Repeal of inconsistent laws

Any laws or parts of laws inconsistent with this subchapter are repealed.

(Feb. 15, 1927, ch. 155, § 7, 44 Stat. 1103.)

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act as not affecting, modifying, repealing, or superseding this subchapter, see section 392 of this title.

### § 148. Powers of State with respect to milk or cream lawfully imported

Nothing in this subchapter is intended nor shall be construed to affect the powers of any State, or any political subdivision thereof, to regulate the shipment of milk or cream into, or the handling, sale, or other disposition of milk or cream in, such State or political subdivision after the milk and/or cream shall have been lawfully imported under the provisions of this subchapter.

(Feb. 15, 1927, ch. 155, § 8, 44 Stat. 1103.)

### § 149. Definitions

When used in this subchapter—

(a) The term "person" means an individual, partnership, association, or corporation.

(b) The term "United States" means the fifty States and the District of Columbia.

(Feb. 15, 1927, ch. 155, § 9, 44 Stat. 1103; June 25, 1959, Pub. L. 86–70, § 19, 73 Stat. 145; July 12, 1960, Pub. L. 86–624, § 15, 74 Stat. 415.)

AMENDMENTS

1960—Subsec. (b). Pub. L. 86–624 substituted "means the fifty States and the District of Columbia" for "means continental United States, including Alaska".

1959—Subsec. (b). Pub. L. 86–70 inserted ", including Alaska" after "continental United States".

## CHAPTER 5—VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS

Sec.
151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments.
152. Importation regulated and prohibited.
153. Inspection of imports; denial of entry and destruction.
154. Regulations for preparation and sale; licenses.
154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria.
155. Permits for importation.
156. Licenses conditioned on permitting inspection; suspension of licenses.
157. Inspection.
158. Offenses; punishment.
159. Enforcement; penalties applicable; Congressional findings.

FEDERAL FOOD, DRUG, AND COSMETIC ACT

By virtue of act June 25, 1938, ch. 675, § 902(c), 52 Stat. 1059 [section 392(b) of this title], nothing contained in section 301 et seq. of this title shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of this chapter.

CROSS REFERENCES

Biological products, regulation, see section 262 of Title 42, The Public Health and Welfare.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 382, 392 of this title; title 15 section 1459; title 35 sections 156, 271.

### § 151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 832; Dec. 23, 1985, Pub. L. 99–198, title XVII, § 1768(a), 99 Stat. 1654.)

CODIFICATION

The sections of this chapter are comprised of the sentences of the eighth paragraph under the heading "Bu-

reau of Animal Industry,'' in the Department of Agriculture Appropriation Act, 1914, as amended.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

AMENDMENTS

1985—Pub. L. 99–198 substituted ''in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States'' for ''from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia''.

EFFECTIVE DATE OF 1985 AMENDMENT

Section 1768(f) of Pub. L. 99–198 provided that:

''(1) Except as provided in paragraph (2), the amendments made by this section [enacting sections 154a and 159 of this title and amending this section and sections 154 and 157 of this title] shall become effective on the date of enactment of this Act [Dec. 23, 1985].

''(2)(A) Subject to subparagraphs (B) through (D), in the case of a person, firm, or corporation preparing, selling, bartering, exchanging, or shipping a virus, serum, toxin, or analogous product during the 12-month period ending on the date of enactment of this Act [Dec. 23, 1985] solely for intrastate commerce or for exportation, such product shall not after such date of enactment, as a result of its not having been licensed or produced in a licensed establishment, be considered in violation of the eighth paragraph of the matter under the heading 'BUREAU OF ANIMAL INDUSTRY' of the Act entitled 'An Act making appropriations for the Department of Agriculture for the fiscal year ending June thirtieth, nineteen hundred and fourteen', approved March 14, 1913 (as amended by this section) [this chapter], until the first day of the 49th month following the date of enactment of this Act.

''(B) The exemption granted by subparagraph (A) may be extended by the Secretary of Agriculture for a period up to 12 months in an individual case on a showing by a person, firm, or corporation of good cause and a good faith effort to comply with such eighth paragraph with due diligence.

''(C) The exemption granted by subparagraph (A) must be claimed by the person, firm, or corporation preparing such product by the first day of the 13th month following the date of enactment of this Act [Dec. 23, 1985], in the form and manner prescribed by the Secretary, unless the Secretary grants an extension of the time to claim such exemption in an individual case for good cause shown.

''(D) On the issuance by the Secretary of a license to such person, firm, or corporation for such product prior to the first day of the 49th month following the date of enactment of this Act [Dec. 23, 1985], or the end of an extension of the exemption granted by the Secretary, the exemption granted by subparagraph (A) shall terminate with respect to such product.''

SHORT TITLE

Act Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 832, which is classified to this chapter, is popularly known as the ''Virus-Serum-Toxin Act''.

APPROPRIATIONS

An appropriation of $25,000 was made by act Mar. 4, 1913, for the purpose of carrying into effect these provisions. The appropriation for the fiscal year 1926 was by act Feb. 10, 1925, ch. 200, 43 Stat. 827.

### § 152. Importation regulated and prohibited

The importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without (1) a permit from the Secretary of Agriculture, or (2) in the case of an article originating in Canada, such permit or, in lieu of such permit, such certification by Canada as may be prescribed by the Secretary of Agriculture.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 832; Sept. 28, 1988, Pub. L. 100–449, title III, § 301(d), 102 Stat. 1868.)

CODIFICATION

See note set out under section 151 of this title.

AMENDMENTS

1988—Pub. L. 100–449 amended section generally. Prior to amendment, section read as follows: ''The importation into the United States, without a permit from the Secretary of Agriculture, of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, are prohibited.''

EFFECTIVE AND TERMINATION DATES OF 1988 AMENDMENT

Amendment by Pub. L. 100–449 effective on the date the United States-Canada Free-Trade Agreement enters into force (Jan. 1, 1989), and to cease to have effect on the date the Agreement ceases to be in force, see section 501(a), (c) of Pub. L. 100–449, set out in a note under section 2112 of Title 19, Customs Duties.

### § 153. Inspection of imports; denial of entry and destruction

The Secretary of Agriculture is authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 832.)

CODIFICATION

See note set out under section 151 of this title.

### § 154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, or otherwise to carry out this chapter, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 832; Dec. 23, 1985, Pub. L. 99–198, title XVII, § 1768(b), 99 Stat. 1654.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

AMENDMENTS

1985—Pub. L. 99–198 inserted ''or otherwise to carry out this chapter,'' after ''domestic animals,''.

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–198 effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as a note under section 151 of this title.

### § 154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria

In order to meet an emergency condition, limited market or local situation, or other special circumstance (including production solely for intrastate use under a State-operated program), the Secretary may issue a special license under an expedited procedure on such conditions as are necessary to assure purity, safety, and a reasonable expectation of efficacy. The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation—

(1) solely for administration to animals of such person, firm, or corporation;

(2) solely for administration to animals under a veterinarian-client-patient relationship in the course of the State licensed professional practice of veterinary medicine by such person, firm, or corporation; or

(3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet criteria under which the State—

(A) may license virus, serum, toxin, and analogous products and establishments that produce such products;

(B) may review the purity, safety, potency, and efficacy of such products prior to licensure;

(C) may review product test results to assure compliance with applicable standards for purity, safety, and potency, prior to release to the market;

(D) may deal effectively with violations of State law regulating virus, serum, toxin, and analogous products; and

(E) exercises the authority referred to in subclauses (A) through (D) consistent with the intent of this chapter of prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products.

(Mar. 4, 1913, ch. 145, § 1 [part], as added Dec. 23, 1985, Pub. L. 99–198, title XVII, § 1768(c), 99 Stat. 1654.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

EFFECTIVE DATE

Section effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as an Effective Date of 1985 Amendment note under section 151 of this title.

### § 155. Permits for importation

The Secretary of Agriculture is authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 833.)

CODIFICATION

See note set out under section 151 of this title.

### § 156. Licenses conditioned on permitting inspection; suspension of licenses

All licenses issued under authority of this chapter to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of said chapter, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 833.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original ''this Act'', meaning act Mar. 4, 1913, ch. 145, 37 Stat. 828, which enacted this chapter, sections 155 and 393 of Title 7, Agriculture, section 316 of Title 15, Commerce and Trade, sections 501, 502, 512, 558, and 560 of Title 16, Conservation, and section 630 of former Title 31, Money and Finance, and amended section 83 of former Title 5, Executive Departments and Government Officers and Employees, and sections 518 and 673 of Title 16.

Section 316 of Title 15 was omitted from the Code as superseded by section 5701 et seq. of Title 5, Government Organization and Employees. Section 630 of former Title 31 was repealed by act Sept. 12, 1950, ch. 946, title III, § 301(64), 64 Stat. 842. Section 83 of former Title 5 was repealed and reenacted as section 5946 of Title 5 by Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 514. For complete classification of act Mar. 4, 1913, to the Code, see Tables.

CODIFICATION

See note set out under section 151 of this title.

### § 157. Inspection

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Sec-

retary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 833; Dec. 23, 1985, Pub. L. 99–198, title XVII, § 1768(d), 99 Stat. 1655.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

AMENDMENTS

1985—Pub. L. 99–198 struck out ''licensed under this chapter'' after ''enter and inspect any establishment''.

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–198 effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as a note under section 151 of this title.

CROSS REFERENCES

Overtime of employees working at establishments which prepare virus, serum, toxin and analogous products, see section 394a of Title 7, Agriculture.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 7 section 394a.

### § 158. Offenses; punishment

Any person, firm, or corporation who shall violate any of the provisions of this chapter shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding $1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(Mar. 4, 1913, ch. 145, § 1 [part], 37 Stat. 833.)

REFERENCES IN TEXT

For explanation of ''this chapter'', referred to in text, see References in Text note set out under section 156 of this title.

CODIFICATION

See note set out under section 151 of this title.

### § 159. Enforcement; penalties applicable; Congressional findings

The procedures of sections 672, 673, and 674 of this title (relating to detentions, seizures and condemnations, and injunctions, respectively) shall apply to the enforcement of this chapter with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of this chapter or a regulation promulgated under this chapter. The provisions (including penalties) of section 675 of this title shall apply to the performance of official duties under this chapter. Congress finds that (i) the products and activities that are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and (ii) regulation of the products and activities as provided in this chapter is necessary to prevent and eliminate burdens on such commerce and to effectively regulate such commerce.

(Mar. 4, 1913, ch. 145, § 1 [part], as added Dec. 23, 1985, Pub. L. 99–198, title XVII, § 1768(e), 99 Stat. 1655.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

EFFECTIVE DATE

Section effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as an Effective Date of 1985 Amendment note under section 151 of this title.

## CHAPTER 5A—BUREAU OF NARCOTICS

### §§ 161 to 165. Omitted

CODIFICATION

Section 161, acts June 14, 1930, ch. 488, § 1, 46 Stat. 585; Oct. 15, 1949, ch. 695, § 6(a), 63 Stat. 881, established a Bureau of Narcotics in the Department of the Treasury and provided for appointment of a Commissioner of Narcotics for the Bureau with duty of making an annual report to Congress.

Section 162, acts June 14, 1930, ch. 488, § 2, 46 Stat. 585; June 26, 1930, ch. 623, § 1, 46 Stat. 819; Oct. 27, 1970, Pub. L. 91–513, title III, § 1101(a)(4), 84 Stat. 1291, provided for appointment and compensation of a deputy commissioner and other personnel for the Bureau of Narcotics, required the deputy to be an acting Commissioner during absence or disability of the Commissioner or a vacancy in the office, and authorized designation of a member of the Treasury Department as an acting Commissioner in event there is no Commissioner or deputy commissioner.

Section 163, act Mar. 3, 1927, ch. 348, § 4(a), 44 Stat. 1382, provided for transfer of control of narcotic drugs to the Secretary of the Treasury from the Commissioner of Internal Revenue and his assistants, agents, and inspectors.

Section 164, acts June 14, 1930, ch. 488, § 3, 46 Stat. 586; June 26, 1930, ch. 623, § 2, 46 Stat. 819; Ex. Ord. No. 6639, Mar. 10, 1934, abolished the Federal Narcotics Control Board and transferred powers of such Board to the Commissioner of Narcotics, authorized the Secretary of the Treasury to confer or impose his duties under section 163 of this title upon the Commissioner or other personnel of the Bureau of Narcotics, continued in effect orders, rules, and regulations in existence on July 1, 1930, until modified, superseded, or repealed by the Commissioner, with approval of the Secretary of the Treasury, and provided for determination before such Bureau of Narcotics of proceedings, investigations, and other matters pending on July 1, 1930 before Bureau of Prohibition or Federal Narcotics Control Board respecting narcotic drug law administration or enforcement. Bureau of Prohibition personnel, records, property, and unexpended balances of appropriations were previously transferred to Bureau of Narcotics as were powers of the Attorney General respecting the Bureau of Prohibition to the Commissioner of Internal Revenue.

Section 165, act June 14, 1930, ch. 488, § 5, 46 Stat. 587, provided for review of decisions of Commissioner of Narcotics by the Secretary of the Treasury.

TRANSFER OF FUNCTIONS

Functions of the Secretary of the Treasury administered through or respecting the Bureau of Narcotics and all functions of the Bureau, the Commissioner of Narcotics, and the officers, employees and agencies of the Bureau were transferred to the Attorney General and the Bureau and the office of Commissioner of Nar-

cotics were abolished by Reorg. Plan No. 1 of 1968, eff. Apr. 8, 1968, 33 F.R. 5611, 82 Stat. 1367, set out in the Appendix to Title 5, Government Organization and Employees. All positions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds of the Bureau and the Treasury Department, in connection with functions transferred under this reorganization plan, were transferred to the Justice Department.

The Bureau of Narcotics and Dangerous Drugs, including the office of Director thereof, in the Department of Justice was abolished by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 2 of 1973 also created in the Department of Justice a single, comprehensive agency for the enforcement of drug laws to be known as the Drug Enforcement Administration, empowered the Attorney General to authorize the performance by officers, employees, and agencies of the Department of functions transferred to him, and directed the Attorney General to coordinate all drug law enforcement functions to assure maximum cooperation between the Drug Enforcement Administration, the Federal Bureau of Investigation, and the other units of the Department of Justice involved in drug law enforcement.

## CHAPTER 6—NARCOTIC DRUGS

EXECUTIVE ORDER NO. 10302

Ex. Ord. No. 10302, Nov. 5, 1951, 16 F.R. 11257, formerly set out as a note preceding section 171, which established the Interdepartmental Committee on Narcotics, was revoked by Ex. Ord. No. 11529, Apr. 24, 1970, 35 F.R. 6697.

### IMPORTATION OR EXPORTATION

### §§ 171 to 174. Repealed. Pub. L. 91–513, title III, § 1101(a)(2), (4), Oct. 27, 1970, 84 Stat. 1291

Section 171, acts Feb. 9, 1909, ch. 100, § 1, 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 14, 1930, ch. 488, § 3, 46 Stat. 586; July 1, 1944, ch. 377, § 8, 58 Stat. 721; Mar. 8, 1946, ch. 81, § 7, 60 Stat. 39; Aug. 8, 1953, ch. 394, § 8, 67 Stat. 506, defined ''narcotic drug'', ''United States'', and ''person''. See section 801 et seq. of this title.

Section 172, acts Feb. 9, 1909, ch. 100, § 2(a), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; June 7, 1924, ch. 352, 43 Stat. 657, established a Federal Narcotics Control Board. Act May 26, 1922, ch. 202, § 1, 42 Stat. 596, also classified to this section, was repealed by Pub. L. 89–554, § 8(a), Sept. 6, 1966, 80 Stat. 645.

Section 173, acts Feb. 9, 1909, ch. 100, § 2(b), (d), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657; June 14, 1930, ch. 488, § 3, 46 Stat. 586, prohibited importation of narcotic drugs. See section 801 et seq. of this title.

Section 173a, act June 14, 1930, ch. 488, § 6, 46 Stat. 587, provided for importation of additional amounts of coca leaves.

Section 174, acts Feb. 9, 1909, ch. 100, § 2(c), (f), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657; Nov. 2, 1951, ch. 666, §§ 1, 5(1), 65 Stat. 767; July 18, 1956, ch. 629, title I, § 105, 70 Stat. 570, set penalties for bringing narcotic drugs into the United States contrary to law. See chapter 13 of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective on first day of seventh calendar month that begins after Oct. 27, 1970, see section 1105(a) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Section 1103 of Pub. L. 91–513 provided that:

''(a) Prosecutions for any violation of law occurring prior to the effective date of section 1101 [the first day of the seventh calendar month that begins after Oct. 26, 1970] shall not be affected by the repeals or amendments made by such section or section 1102 [repealing sections 171 to 174, 176 to 185, 188 to 188n, 191 to 193, 197, 198, 199, 501 to 517 of this title, sections 1401 to 1407, and 3616 of Title 18, Crimes and Criminal Procedure, sections 4701 to 4707, 4711 to 4716, 4721 to 4726, 4731 to 4736, 4741 to 4746, 4751 to 4757, 4761, 4762, 4771 to 4776, 7237, 7238, and 7491 of Title 26, Internal Revenue Code, sections 529a and 529g of former Title 31, Money and Finance, and section 1421m of Title 48, Territories and Insular Possessions, and amending sections 162 and 967 of this title, section 4251 of Title 18, section 1584 of Title 19, Customs Duties, sections 4901, 4905, 6808, 7012, 7103, 7236, 7607, 7609, 7641, 7651, and 7655 of Title 26, section 2901 of Title 28, Judiciary and Judicial Procedure, sections 529d, 529e, and 529f of former Title 31, section 304m of Title 40, Public Buildings, Property, and Works, section 3411 of Title 42, The Public Health and Welfare, section 239a of Title 46, Shipping, and section 787 of former Title 49, Transportation], or abated by reason thereof.

''(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 1101 [the first day of the seventh calendar month that begins after Oct. 26, 1970] shall not be affected by the repeals or amendments made by such section or section 1102, or abated by reason thereof.''

### § 175. Repealed. June 27, 1952, ch. 477, title IV, § 403(a)(10), 66 Stat. 279

Section, acts Feb. 9, 1909, ch. 100, § 2(e), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657, related to deportation of convicted aliens. See section 1251 et seq. of Title 8, Aliens and Nationality.

### §§ 176 to 185. Repealed. Pub. L. 91–513, title III, § 1101(a)(2), (9), Oct. 27, 1970, 84 Stat. 1291, 1292

Section 176, acts Feb. 9, 1909, ch. 100, § 2(g), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202 § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657, covered liability of masters of vessels and persons in charge of railroad cars and other vehicles used to carry narcotic drugs.

Section 176a, act Feb. 9, 1909, ch. 100, § 2(h), as added July 18, 1956, ch. 629, title I, § 106, 70 Stat. 570, covered illegal importation of marihuana and set penalties for such illegal importation. See section 801 et seq. of this title.

Section 176b, act Feb. 9, 1909, ch. 100, § 2(i), as added July 18, 1956, ch. 629, title I, § 107, 70 Stat. 571, prohibited sale of heroin to juveniles and set penalties for such illegal sale. See section 801 et seq. of this title.

Section 177, acts Feb. 9, 1909, ch. 100, § 2(a), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657, vested administration of Narcotic Drugs Import and Export Act in Department of the Treasury.

Section 178, act Feb. 9, 1909, ch. 100, § 4, as added Jan. 17, 1914, ch. 9, 38 Stat. 275, prohibited possession of smoking opium. See section 801 et seq. of this title.

Section 179, act Feb. 9, 1909, ch. 100, § 4, as added Jan. 17, 1914, ch. 9, 38 Stat. 275, covered liability of masters of vessels and persons in charge of railroad cars or other vehicles for possession of smoking heroin. See section 801 et seq. of this title.

Section 180, act Feb. 9, 1909, ch. 100, § 5, as added Jan. 17, 1914, ch. 9, 38 Stat. 275; amended May 26, 1922, ch. 202, § 2, 42 Stat. 597; June 14, 1930, ch. 488, § 3, 46 Stat. 586, prohibited admission of smoking opium even for transportation to another country or for transferal from one vessel to another.

Section 181, act Feb. 9, 1909, ch. 100, § 3, as added Jan. 17, 1914, ch. 9, 38 Stat. 275, created a presumption of ille-

gal importation based upon presence of smoking opium in United States.

Section 182, act Feb. 9, 1909, ch. 100, § 6, as added Jan. 17, 1914, ch. 9, 348 Stat. 275; amended May 26, 1922, ch. 202, § 2, 42 Stat. 597; June 14, 1930, ch. 488, § 3, 46 Stat. 586; Apr. 22, 1960, Pub. L. 86–429, § 15, 74 Stat. 66, forbade exportation of narcotic drugs. See section 801 et seq. of this title.

Section 183, act Feb. 9, 1909, ch. 100, § 7, as added Jan. 17, 1914, ch. 9, 38 Stat. 277, set out penalties for illegal exportation of narcotic drugs.

Section 184, act Feb. 9, 1909, ch. 100, § 8, as added Jan. 17, 1914, ch. 9, 38 Stat. 277; amended May 26, 1922, ch. 202, § 3, 42 Stat. 598, provided for seizure and forfeiture of narcotic drugs found on vessels and not shown on manifest or landed from vessels without a permit.

Section 184a, acts July 11, 1941, ch. 289, § 1, 55 Stat. 584; July 18, 1956, ch. 629, title I, § 108, 70 Stat. 571, made illegal bringing on board a vessel of United States any narcotic drugs not constituting a part of the cargo.

Section 185, act Feb. 9, 1909, ch. 100, § 9, as added May 26, 1922, ch. 202, § 4, 42 Stat. 598, authorized the citation of act Feb. 9, 1909, ch. 100, as the ''Narcotic Drugs Import and Export Act''.

EFFECTIVE DATE OF REPEAL

Repeal effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91–513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91–513, set out as a note under sections 171 to 174 of this title.

## MARIHUANA AND HEALTH REPORTING

### §§ 186, 187. Transferred

CODIFICATION

Section 186, Pub. L. 91–296, title V, § 501, June 30, 1970, 84 Stat. 352, which related to congressional findings as to marihuana use, the need for a better understanding of the health consequences, and the lack of information thereto, was transferred and set out as a note under section 242 of Title 42, The Public Health and Welfare.

Section 187, Pub. L. 91–296, title V, § 502, June 30, 1970, 84 Stat. 352, which directed the Secretary of Health, Education and Welfare to report to Congress on the current information on the health consequence of marihuana use, with recommendations for legislative and administrative action and to submit a preliminary report no later than 90 days after June 30, 1970, was transferred and set out as a note under section 242 of Title 42.

## DOMESTIC CONTROL OF PRODUCTION AND DISTRIBUTION OF THE OPIUM POPPY

### §§ 188 to 188n. Repealed. Pub. L. 91–513, title III, § 1101(a)(7), Oct. 27, 1970, 84 Stat. 1292

Sections, acts Dec. 11, 1942, ch. 720, 56 Stat. 1045; June 25, 1959, Pub. 86–70, § 20, 73 Stat. 145; July 12, 1960, Pub. L. 86–624, § 16, 74 Stat. 415, known as the ''Opium Poppy Control Act of 1942'', provided for the domestic control of production and distribution of the opium poppy. Sections 1 to 17 of said Act of Dec. 11, 1942, were classified, respectively, to sections 188, 188 notes, and 188a to 188n of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91–513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91–513, set out as a note under section 171 of this title.

## IMPORTATION BY CHINESE SUBJECTS OR TRAFFICKING IN, IN CHINA, BY UNITED STATES CITIZENS

### §§ 191 to 193. Repealed. Pub. L. 91–513, title III, § 1101(a)(1), Oct. 27, 1970, 84 Stat. 1291

Sections, acts Feb. 23, 1887, ch. 210, 24 Stat. 409; June 25, 1948, ch. 646, §§ 5, 39, 62 Stat. 986, 992, prohibited importation of opium by Chinese subjects and the trafficking in, in China, of opium by United States citizens. Sections 1 to 3 of said Act of Feb. 23, 1887, were classified to sections 191 to 193, respectively, of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91–513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91–513, set out as a Savings Provision note under section 171 of this title.

## MISCELLANEOUS

### § 196. Repealed. July 1, 1944, ch. 373, title XIII, § 1313, 58 Stat. 714

Section, act June 14, 1930, ch. 488, § 4(b), (c), 46 Stat. 587; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, related to studies and investigations by Surgeon General of the Public Health Service. See section 242 of Title 42, The Public Health and Welfare.

RENUMBERING OF REPEALING ACT

Section 611 of act July 1, 1944, which repealed this section, was renumbered 711 by act Aug. 13, 1946, ch. 958, § 5, 60 Stat. 1049, 713 by act Feb. 28, 1948, ch. 83, § 9(b), 62 Stat. 47, 813 by act July 30, 1956, ch. 779, § 3(b), 70 Stat. 720, 913 by Pub. L. 88–581, § 4(b), Sept. 4, 1964, 78 Stat. 919, 1013 by Pub. L. 89–239, § 3(b), Oct. 6, 1965, 79 Stat. 931, 1113 by Pub. L. 91–572, § 6(b), Dec. 24, 1970, 84 Stat. 1506, 1213 by Pub. L. 92–294, § 3(b), May 16, 1972, 86 Stat. 137, 1313 by Pub. L. 93–154, § 2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, § 7(b), Dec. 29, 1973, 87 Stat. 936.

### §§ 197, 198. Repealed. Pub. L. 91–513, title III, § 1101(a)(4), Oct. 27, 1970, 84 Stat. 1291

Section 197, act June 14, 1930, ch. 488, § 7, 46 Stat. 587, directed Secretary of the Treasury to cooperate with Secretary of State in discharge of international obligations of United States concerning traffic in narcotic drugs.

Section 198, acts June 14, 1930, ch. 488, § 8, 46 Stat. 587; July 18, 1956, ch. 629, title III, § 302, 70 Stat. 575, directed Secretary of the Treasury to cooperate with the several States in suppression of abuse of narcotic drugs in their respective jurisdictions.

EFFECTIVE DATE OF REPEAL

Repeal effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91–513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91–513, set out as a note under sections 171 to 174 of this title.

### §§ 198a to 198c. Transferred

CODIFICATION

Section 198a, act Aug. 11, 1955, ch. 800, § 1, 69 Stat. 684, as amended, which related to the authority of Secretary of the Treasury to issue subpenas, administer oaths and compel attendance of witnesses for purpose of any investigation, was transferred to section 967 of this title.

Section 198b, act Aug. 11, 1955, ch. 800, § 2, 69 Stat. 685, which related to service of subpenas and proof of service, was transferred to section 968 of this title.

Section 198c, act Aug. 11, 1955, ch. 800, § 3, 69 Stat. 685, which related to contempt proceedings, was transferred to section 969 of this title.

### § 199. Repealed. Pub. L. 91–513, title III, § 1101(a)(5), Oct. 27, 1970, 84 Stat. 1292

Section, act July 3, 1930, ch. 829, 46 Stat. 850, authorized payment to persons giving information concerning violations of narcotics laws. See section 886(a) of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of this section by section 1101 of Pub. L. 91–513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91–513, set out as a note under section 171 of this title.

### §§ 200 to 200b. Repealed. Nov. 2, 1951, ch. 666, § 5(2), 65 Stat. 769

Sections, acts Aug. 12, 1937, ch. 598, §§ 1–3, 50 Stat. 627; July 1, 1944, ch. 377, § 9, 58 Stat. 721; Mar. 8, 1946, ch. 81, § 8, 60 Stat. 39, related to punishment for offenses after first offense. See section 801 et seq. of this title.

SAVINGS PROVISION

Section 6 of act Nov. 2, 1951, provided that any rights or liabilities now existing under former sections 200 to 200b of this title should not be affected by their repeal.

## CHAPTER 7—PRACTICE OF PHARMACY AND SALE OF POISONS IN CONSULAR DISTRICTS IN CHINA

Sec.
201. Doing business without a license unlawful; employment of Chinese subjects.
202. Certain classes of persons and corporations excepted; insecticides.
203. Application for license; requirements; qualifications for license.
204. Issuance of license.
205. Display of license in pharmacy.
206. Revocation of license.
207. Restrictions on sales; written orders or prescriptions.
208. Certain preparations and sales excepted.
209. Poisons; book entry of sale; labels.
210. Pharmacist; unauthorized use of title.
211. Preservation of originals of prescriptions compounded and copies thereof; inspection of prescriptions by consular officers; marking containers of drugs.
212. Offenses; punishment; duty to enforce provisions.
213. Fraudulent representations to evade or defeat restrictions.
214. Previous laws unaffected.
215. ''Consul'' defined.

### § 201. Doing business without a license unlawful; employment of Chinese subjects

It shall be unlawful in the consular districts of the United States in China for any person whose permanent allegiance is due to the United States not licensed as a pharmacist within the meaning of this chapter to conduct or manage any pharmacy, drug or chemical store, apothecary shop, or other place of business for the retailing, compounding, or dispensing of any drugs, chemicals, or poisons, or for the compounding of physicians' prescriptions, or to keep exposed for sale at retail, any drugs, chemicals, or poisons, except as hereinafter provided, or, except as hereinafter provided, for any person whose permanent allegiance is due to the United States not licensed as a pharmacist within the meaning of this chapter to compound, dispense, or sell, at retail, any drug, chemical, poison, or pharmaceutical preparation upon the prescription of a physician, or otherwise, or to compound physicians' prescriptions, except as an aid to and under the proper supervision of a pharmacist licensed under this chapter. And it shall be unlawful for any person, firm, or corporation owing permanent allegiance to the United States owning partly or wholly or managing a pharmacy, drug store, or other place of business to cause or permit any person other than a licensed pharmacist to compound, dispense, or sell at retail any drug, medicine, or poison, except as an aid to and under the proper supervision of a licensed pharmacist. Where it is necessary for a person, firm, or corporation whose permanent allegiance is due to the United States and owning partly or wholly or managing a pharmacy, drug store, or other place of business to employ Chinese subjects to compound, dispense, or sell at retail any drug, medicine, or poison, such person, firm, or corporation, owner, part owner, or manager of a pharmacy, drug store, or other place of business may employ such Chinese subjects when their character, ability, and age of twenty-one years or over have been certified to by at least two recognized and reputable practitioners of medicine, or two pharmacists licensed under this chapter whose permanent allegiance is due to the United States.

(Mar. 3, 1915, ch. 74, § 1, 38 Stat. 817.)

CODIFICATION

Section is comprised of part of section 1 of act Mar. 3, 1915. Remainder of such section 1 is classified to section 202 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 202 of this title.

### § 202. Certain classes of persons and corporations excepted; insecticides

Nothing in section 201 of this title shall be construed to interfere with any recognized and reputable practitioner of medicine, dentistry, or veterinary surgery in the compounding of his own prescriptions, or to prevent him from supplying to his patients such medicines as he may deem proper, except as hereinafter provided; nor with the exclusively wholesale business of any person, firm, or corporation whose permanent allegiance is due to the United States dealing and licensed as pharmacists, or having in their employ at least one person who is so licensed, except as hereinafter provided; nor with the sale by persons, firms, or corporations whose permanent allegiance is due to the United States other than pharmacists of poisonous substances sold exclusively for use in the arts, or as insecticides, when such substances are sold in unbroken packages bearing labels having plainly printed upon them the name of the contents, the word ''Poison'', when practicable the name of at least one suitable antidote, and the name and address of the vender.

(Mar. 3, 1915, ch. 74, § 1, 38 Stat. 818.)

CODIFICATION

Section is comprised of part of section 1 of act Mar. 3, 1915. Remainder of such section 1 is classified to section 201 of this title.

### § 203. Application for license; requirements; qualifications for license

Every person whose permanent allegiance is due to the United States desiring to practice as a pharmacist in the consular districts in China shall file with the consul an application, duly verified under oath, setting forth the name and age of the applicant, the place or places at which he pursued and the time spent in the study of pharmacy, the experience which the applicant has had in compounding physicians' prescriptions under the direction of a licensed pharmacist, and the name and location of the school or college of pharmacy, if any, of which he is a graduate, and shall submit evidence sufficient to show to the satisfaction of said consul that he is of good moral character and not addicted to the use of alcoholic liquors or narcotic drugs so as to render him unfit to practice pharmacy. Applicants shall be not less than twenty-one years of age and shall have had at least four years' experience in the practice of pharmacy or shall have served three years under the instruction of a regularly licensed pharmacist, and any applicant who has been graduated from a school or college of pharmacy recognized by the proper board of his State, Territory, District of Columbia, or other possession of the United States as in good standing shall be entitled to practice upon presentation of his diploma.

(Mar. 3, 1915, ch. 74, § 2, 38 Stat. 818.)

CODIFICATION

The words ''now practicing as a pharmacist or,'' which preceded ''desiring to practice'' in the original text of this section, were omitted as obsolete.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 204 of this title.

### § 204. Issuance of license

If the applicant for license as a pharmacist has complied with the requirements of section 203 of this title, the consul shall issue to him a license which shall entitle him to practice pharmacy in the consular districts of the United States in China, subject to the provisions of this chapter.

(Mar. 3, 1915, ch. 74, § 3, 38 Stat. 819.)

### § 205. Display of license in pharmacy

Every license to practice pharmacy shall be conspicuously displayed by the person to whom the same has been issued in the pharmacy, drug store, or place of business, if any, of which the said person is the owner or part owner or manager.

(Mar. 3, 1915, ch. 74, § 5, 38 Stat. 819.)

### § 206. Revocation of license

The license of any person whose permanent allegiance is due to the United States to practice pharmacy in the consular districts of the United States in China may be revoked by the consul if such person be found to have obtained such license by fraud, or be addicted to the use of any narcotic or stimulant, or to be suffering from physical or mental disease, in such manner and to such extent as to render it expedient that in the interests of the public his license be canceled; or to be of an immoral character; or if such person be convicted in any court of competent jurisdiction of any offense involving moral turpitude. It shall be the duty of the consul to investigate any case in which it is discovered by him or made to appear to his satisfaction that any license issued under the provisions of this chapter is revocable and shall, after full hearing, if in his judgment the facts warrant it, revoke such license.

(Mar. 3, 1915, ch. 74, § 4, 38 Stat. 819.)

### § 207. Restrictions on sales; written orders or prescriptions

It shall be unlawful for any person, firm, or corporation whose permanent allegiance is due to the United States, either personally or by servant or agent or as the servant or agent of any other person or of any firm or corporation, to sell, furnish, or give away any cocaine, salts of cocaine, or preparation containing cocaine or salts of cocaine, or morphine or preparation containing morphine or salts of morphine, or any opium or preparation containing opium, or any chloral hydrate or preparation containing chloral hydrate, except upon the original written order or prescription of a recognized and reputable practitioner of medicine, dentistry, or veterinary medicine, which order or prescription shall be dated and shall contain the name of the person for whom prescribed, or, if ordered by a practitioner of veterinary medicine, shall state the kind of animal for which ordered and shall be signed by the person giving the order or prescription. Such order or prescription shall be, for a period of three years, retained on file by

the person, firm, or corporation who compounds or dispenses the article ordered or prescribed, and it shall not be compounded or dispensed after the first time except upon the written order of the original prescriber.

(Mar. 3, 1915, ch. 74, § 6, 38 Stat. 819.)

CODIFICATION

Section is comprised of part of section 6 of act Mar. 3, 1915. Remainder of such section 6 is classified to section 208 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 208, 211 of this title.

### § 208. Certain preparations and sales excepted

The provisions of section 207 of this title shall not apply to preparations containing not more than two grains of opium or not more than one-quarter grain of morphine, or not more than one-quarter grain of cocaine, or not more than two grains of chloral hydrate in the fluid ounce, or, of a solid preparation, in one avoirdupois ounce, nor shall they apply to preparations sold in good faith for diarrhea and cholera, each bottle or package of which is accompanied by specific directions for use and caution against habitual use, nor to liniments or ointments sold in good faith as such when plainly labeled ''for external use only'', nor to powder of ipecac and opium, commonly known as Dover's powder, when sold in quantities not exceeding twenty grains. The provisions of this section or section 207 of this title shall not be construed to permit the selling, furnishing, giving away, or prescribing for the use of any habitual users of the same any cocaine, salts of cocaine, or preparation containing cocaine or salts of cocaine, or morphine or salts of morphine, or preparations containing morphine or salts of morphine, or any opium or preparation containing opium, or any chloral hydrate or preparation containing chloral hydrate. But the preceding sentence shall not be construed to prevent any recognized or reputable practitioner of medicine whose permanent allegiance is due to the United States from furnishing in good faith for the use of any habitual user of narcotic drugs who is under his professional care such substances as he may deem necessary for their treatment, when such prescriptions are not given or substances furnished for the purpose of evading the provisions of this section. But the provisions of this section or section 207 of this title shall not apply to sales at wholesale between jobbers, manufacturers, and retail druggists, hospitals, and scientific or public institutions.

(Mar. 3, 1915, ch. 74, § 6, 38 Stat. 819.)

CODIFICATION

Section is comprised of section 6 of act Mar. 3, 1915. Remainder of such section 6 is classified to section 207 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 211 of this title.

### § 209. Poisons; book entry of sale; labels

It shall be unlawful for any person, firm, or corporation whose permanent allegiance is due to the United States to sell or deliver to any other person any of the following-described substances, or any poisonous compound, combination, or preparation thereof, to wit: The compounds of and salts of antimony, arsenic, barium, chromium, copper, gold, lead, mercury, silver, and zinc, the caustic hydrates of sodium and potassium, solution or water of ammonia, methyl alcohol, paregoric, the concentrated mineral acids, oxalic and hydrocyanic acids and their salts, yellow phosphorus, Paris green, carbolic acid, the essential oils of almonds, pennyroyal, tansy, rue, and savin; croton oil, creosote, chloroform, cantharides, or aconite, belladonna, bitter almonds, colchicum, cotton root, cocculus indicus, conium, cannabis indica, digitalis, ergot, hyoscyamus, ignatia, lobelia, nux vomica, physostigma, phytolacca, strophanthus, stramonium, veratrum viride, or any of the poisonous alkaloids or alkaloidal salts derived from the foregoing, or any other poisonous alkaloids or their salts, or any other virulent poison, except in the manner following, and, moreover, if the applicant be less than eighteen years of age, except upon the written order of a person known or believed to be an adult.

It shall first be learned, by due inquiry, that the person to whom delivery is about to be made is aware of the poisonous character of the substance and that it is desired for a lawful purpose, and the box, bottle, or other package shall be plainly labeled with the name of the substance, the word ''Poison'', the name of at least one suitable antidote, when practicable, and the name and address of the person, firm, or corporation dispensing the substance. And before delivery be made of any of the foregoing substances, excepting solution or water of ammonia and sulphate of copper, there shall be recorded in a book kept for that purpose the name of the article, the quantity delivered, the purpose for which it is to be used, the date of delivery, the name and address of the person for whom it is procured, and the name of the individual personally dispensing the same; and said book shall be preserved by the owner thereof for at least three years after the date of the last entry therein. The foregoing provisions shall not apply to articles dispensed upon the order of persons believed by the dispenser to be recognized and reputable practitioners of medicine, dentistry, or veterinary surgery. When a physician writes upon his prescription a request that it be marked or labeled ''Poison'' the pharmacist shall, in the case of liquids, place the same in a colored glass, roughened bottle, of the kind commonly known in trade as a ''poison bottle'', and, in the case of dry substances, he shall place a poison label upon the container. The record of sale and delivery above mentioned shall not be required of manufacturers and wholesalers who shall sell any of the foregoing substances at wholesale to licensed pharmacists, but the box, bottle, or other package containing such substance, when sold at wholesale, shall be properly labeled with the name of the substance, the word ''poison'', and the name and address of the manufacturer or wholesaler. It shall not be necessary, in sales either at wholesale or at retail, to place a poison label upon, nor to record the delivery of, the sulphide of antimony, or the oxide or carbonate of

zinc, or of colors ground in oil and intended for use as paints, or calomel; nor in the case of preparations containing any of the substances named in this section, when a single box, bottle, or other package, or when the bulk of one-half fluid ounce or the weight of one-half avoirdupois ounce does not contain more than an adult medicinal dose of such substance; nor in the case of liniments or ointments sold in good faith as such, when plainly labeled ''For external use only''; nor, in the case of preparations put up and sold in the form of pills, tablets, or lozenges, containing any of the substances enumerated in this section and intended for internal use, when the dose recommended does not contain more than one-fourth of an adult medicinal dose of such substance.

For the purpose of this and of every other section of this chapter no box, bottle, or other package shall be regarded as having been labeled ''Poison'' unless the word ''Poison'' appears conspicuously thereon, printed in plain, uncondensed gothic letters in red ink.

(Mar. 3, 1915, ch. 74, § 7, 38 Stat. 820.)

### § 210. Pharmacist; unauthorized use of title

It shall be unlawful for any person whose permanent allegiance is due to the United States, not legally licensed as a pharmacist, to take, use, or exhibit the title of pharmacist, or licensed or registered pharmacist, or the title of druggist or apothecary, or any other title or description of like import.

(Mar. 3, 1915, ch. 74, § 10, 38 Stat. 821.)

### § 211. Preservation of originals of prescriptions compounded and copies thereof; inspection of prescriptions by consular officers; marking containers of drugs

Every person, firm, or corporation whose permanent allegiance is due to the United States owning, partly owning, or managing a drug store or pharmacy shall keep in his place of business a suitable book or file, in which shall be preserved for a period of not less than three years the original of every prescription compounded or dispensed at such store or pharmacy, or a copy of such prescription, except when the preservation of the original is required by section 207 or 208 of this title. Upon request the owner, part owner, or manager of such store shall furnish to the prescribing physician, or to the person for whom such prescription was compounded or dispensed, a true and correct copy thereof. Any prescription required by section 207 or 208 of this title, and any prescription for, or register of sales of, substances mentioned in such sections shall at all times be open to inspection by duly authorized consular officers in the consular districts of the United States in China. No person, firm, or corporation whose permanent allegiance is due to the United States shall, in a consular district, compound or dispense any drug or drugs or deliver the same to any other person without marking on the container thereof the name of the drug or drugs contained therein and directions for using the same.

(Mar. 3, 1915, ch. 74, § 9, 38 Stat. 821.)

### § 212. Offenses; punishment; duty to enforce provisions

Any person, firm, or corporation, whose permanent allegiance is due to the United States, violating any of the provisions of this chapter shall be deemed guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than $50 and not more than $100 or by imprisonment for not less than one month and not more than sixty days, or by both such fine and imprisonment, in the discretion of the court, and if the offense be continuing in its character, each week or part of a week during which it continues shall constitute a separate and distinct offense. And it shall be the duty of the consular and judicial officers of the United States in China to enforce the provisions of this chapter.

(Mar. 3, 1915, ch. 74, § 11, 38 Stat. 821.)

### § 213. Fraudulent representations to evade or defeat restrictions

No person, firm, or corporation whose permanent allegiance is due to the United States seeking to procure in the consular districts of the United States in China any substance the sale of which is regulated by the provisions of this chapter shall make any fraudulent representations so as to evade or defeat the restrictions herein imposed.

(Mar. 3, 1915, ch. 74, § 8, 38 Stat. 821.)

### § 214. Previous laws unaffected

Nothing in this chapter shall be construed as modifying or revoking any of the provisions of sections 191 to 193[1] of this title.

(Mar. 3, 1915, ch. 74, § 13, 38 Stat. 822.)

REFERENCES IN TEXT

Sections 191 to 193 of this title, referred to in text, were repealed by Pub. L. 91–513, title III, § 1101(a)(1), Oct. 27, 1970, 84 Stat. 1291. See section 801 et seq. of this title.

### § 215. "Consul" defined

The word ''consul'' as used in this chapter shall mean the consular officer in charge of the district concerned.

(Mar. 3, 1915, ch. 74, § 12, 38 Stat. 822.)

## CHAPTER 8—NARCOTIC FARMS

### §§ 221 to 237. Repealed. July 1, 1944, ch. 373, title XIII, § 1313, 58 Stat. 714

Section 221, act Jan. 19, 1929, ch. 82, § 1, 45 Stat. 1085, defined ''habit-forming narcotic drug'', ''narcotic'', and ''addict''. See section 201 of Title 42, The Public Health and Welfare.

Section 222, act Jan. 19, 1929, ch. 82, § 2, 45 Stat. 1085, provided for narcotic farms. See section 257 of Title 42.

Section 222a, act June 23, 1935, ch. 725, § 1, 49 Stat. 1840, provided name for narcotic farm at Lexington, Ky.

Section 222b, act Mar. 28, 1938, ch. 55, § 1, 52 Stat. 134, provided name for narcotic farm at Fort Worth, Texas.

Section 223, act Jan. 19, 1929, ch. 82, § 3, 45 Stat. 1085; 1939 Reorg. Plan No. I, § 205(b), eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1425, provided for an annual estimate of expenses of maintenance of narcotic farms.

[1] See References in Text note below.

Section 224, act Jan. 19, 1929, ch. 82, §4, 45 Stat. 1086, provided for construction of buildings for two of the narcotic farms.

Section 225, act Jan. 19, 1929, ch. 82, §5, 45 Stat. 1086; June 14, 1930, ch. 488, §4(a), 46 Stat. 586; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, provided for control and management of narcotic farms.

Section 226, act Jan. 19, 1929, ch. 82, §6, 45 Stat. 1086; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for care and treatment of addicts. See section 257 of Title 42.

Section 227, act Jan. 19, 1929, ch. 82, §7, 45 Stat. 1086, provided for transfer to and from farms of addicts who are prisoners. See section 259 of Title 42.

Section 228, act Jan. 19, 1929, ch. 82, §8, 45 Stat. 1087, provided that it was the duty of prosecuting officers to report convicted persons believed to be addicts. See section 259 of Title 42.

Section 229, act Jan. 19, 1929, ch. 82, §9, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for employment of addicts. See section 258 of Title 42.

Section 230, act Jan. 19, 1929, ch. 82, §10, 45 Stat. 1087, provided for parole of inmates. See section 259 of Title 42.

Section 231, act Jan. 19, 1929, ch. 82, §11, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for discharge of addicts. See section 259 of Title 42.

Section 232, act Jan. 19, 1929, ch. 82, §12, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for admission of voluntary patients. See section 260 of Title 42.

Section 233, act Jan. 19, 1929, ch. 82, §13, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for furnishing of gratuities and transportation to discharged convicts. See section 259 of Title 42.

Section 234, act. Jan. 19, 1929, ch. 82, §14, 45 Stat. 1089; 1939 Reorg. Plan No. I, §§201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided penalties for introduction of narcotic drugs into a narcotic farm. See section 261 of Title 42.

Section 235, act Jan. 19, 1929, ch. 82, §15, 45 Stat. 1089, provided penalties for escape of inmates. See section 261 of Title 42.

Section 236, act Jan. 19, 1929, ch. 82, §16, 45 Stat. 1089, provided penalties for procuring of escape by inmates. See section 261 of Title 42.

Section 237, act Jan. 19, 1929, ch. 82, §17, 45 Stat. 1089, provided for deportation of alien inmates who are entitled to a discharge from narcotic farms.

RENUMBERING OF REPEALING ACT

Section 611 of act July 1, 1944, which repealed this section, was renumbered §711 by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049, §713 by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47, §813 by act July 30, 1956, ch. 779, §3(b), 70 Stat. 720, §913 by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919, §1013 by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931, §1113 by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506, §1213 by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137, §1313 by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

## CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER I—SHORT TITLE

Sec.
301. Short title.

SUBCHAPTER II—DEFINITIONS

321. Definitions; generally.
321a. ''Butter'' defined.
321b. ''Package'' defined.
321c. Nonfat dry milk; ''milk'' defined.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

331. Prohibited acts.
332. Injunction proceedings.
(a) Jurisdiction of courts.
(b) Violation of injunction.
333. Penalties.
(a) Violation of section 331 of this title; second violation; intent to defraud or mislead.
(b) Prescription drug marketing violations.
(c) Exceptions in certain cases of good faith, etc.
(d) Exceptions involving misbranded food.
(e) Prohibited distribution of human growth hormone.
(f) Violations related to devices.
333a. Repealed.
334. Seizure.
(a) Grounds and jurisdiction.
(b) Procedure; multiplicity of pending proceedings.
(c) Availability of samples of seized goods prior to trial.
(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures.
(e) Costs.
(f) Removal of case for trial.
(g) Administrative restraint; detention orders.
335. Hearing before report of criminal violation.
335a. Debarment, temporary denial of approval, and suspension.
(a) Mandatory debarment.
(b) Permissive debarment.
(c) Debarment period and considerations.
(d) Termination of debarment.
(e) Publication and list of debarred persons.
(f) Temporary denial of approval.
(g) Suspension authority.
(h) Termination of suspension.
(i) Procedure.
(j) Judicial review.
(k) Certification.
(*l*) Applicability.
335b. Civil penalties.
(a) In general.
(b) Procedure.
(c) Judicial review.
(d) Recovery of penalties.
(e) Informants.
335c. Authority to withdraw approval of abbreviated drug applications.
(a) In general.
(b) Procedure.
(c) Applicability.
(d) Judicial review.
336. Report of minor violations.
337. Proceedings in name of United States; provision as to subpoenas.

SUBCHAPTER IV—FOOD

341. Definitions and standards for food.
342. Adulterated food.
(a) Poisonous, insanitary, etc., ingredients.
(b) Absence, substitution, or addition of constituents.
(c) Color additives.
(d) Confectionery containing alcohol or nonnutritive substance.
(e) Oleomargarine containing filthy, putrid, etc., matter.

Sec.
(f) Dietary supplement or ingredient: safety.
(g) Dietary supplement: manufacturing practices.
343. Misbranded food.
(a) False or misleading label.
(b) Offer for sale under another name.
(c) Imitation of another food.
(d) Misleading container.
(e) Package form.
(f) Prominence of information on label.
(g) Representation as to definition and standard of identity.
(h) Representation as to standards of quality and fill of container.
(i) Label where no representation as to definition and standard of identity.
(j) Representation for special dietary use.
(k) Artificial flavoring, artificial coloring, or chemical preservatives.
(*l*) Pesticide chemicals on raw agricultural commodities.
(m) Color additives.
(n) Packaging or labeling of drugs in violation of regulations.
(*o*) Saccharin for immediate consumption.
(p) Saccharin not for immediate consumption.
(q) Nutrition information.
(r) Nutrition levels and health-related claims.
(s) Dietary supplements.
343–1. National uniform nutrition labeling.
343–2. Dietary supplement labeling exemptions.
(a) In general.
(b) Application.
(c) Burden of proof.
343a. Health risks presented by use of saccharin.
(a) Statement on vending machines dispensing food containing saccharin respecting health risk; regulations.
(b) Availability and distribution of information; review and revision.
344. Emergency permit control.
(a) Conditions on manufacturing, processing, etc., as health measure.
(b) Violation of permit; suspension and reinstatement.
(c) Inspection of permit-holding establishments.
345. Regulations making exemptions.
346. Tolerances for poisonous or deleterious substances in food; regulations.
346a. Tolerances for pesticide chemicals in or on raw agricultural commodities.
(a) Conditions of safety.
(b) Establishment of tolerances.
(c) Exemptions.
(d) Regulations pursuant to petition; publication of notice; time for issuance; referral to advisory committees; effective date; hearings.
(e) Regulations pursuant to Administrator's proposals.
(f) Data submitted as confidential.
(g) Advisory committees; appointment; composition; compensation; clerical assistance.
(h) Right of consultation.
(i) Judicial review.
(j) Temporary tolerances.
(k) Regulations based on public hearings before January 1, 1953.
(*l*) Pesticides under Federal Insecticide, Fungicide, and Rodenticide Act; functions of Administrator of the Environmental Protection Agency; certifications; hearing; time limitation; opinion; regulations.

Sec.
(m) Amendment of regulations.
(n) Guaranties.
(*o*) Payment of fees; services or functions as conditioned on; waiver or refund of fees.
346b. Authorization of appropriations.
347. Intrastate sales of colored oleomargarine.
(a) Law governing.
(b) Labeling and packaging requirements.
(c) Sales in public eating places.
(d) Exemption from labeling requirements.
(e) Color content of oleomargarine.
347a. Congressional declaration of policy regarding oleomargarine sales.
347b. Contravention of State laws.
348. Food additives.
(a) Unsafe food additives; exception for conformity with exemption or regulation.
(b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation.
(c) Approval or denial of petition; time for issuance of order; evaluation of data; factors.
(d) Regulation issued on Secretary's initiative.
(e) Publication and effective date of orders.
(f) Objections and public hearing; basis and contents of order; statement.
(g) Judicial review.
(h) Amendment or repeal of regulations.
(i) Exemptions for investigational use.
349. Bottled drinking water standards; publication in Federal Register.
350. Vitamins and minerals.
(a) Authority and limitations of Secretary; applicability.
(b) Labeling and advertising requirements for foods.
(c) Definitions.
350a. Infant formulas.
(a) Adulteration.
(b) Requirements for quality factors, good manufacturing practices, and retention of records.
(c) Registration of persons distributing new infant formula.
(d) Submission of information about new infant formula required.
(e) Additional notice requirements for manufacturer.
(f) Procedures applicable to recalls by manufacturer; regulatory oversight.
(g) Recordkeeping requirements for manufacturer; regulatory oversight and enforcement.
(h) Exemptions; regulatory oversight.
(i) Nutrient requirements.
350b. New dietary ingredients.
(a) In general.
(b) Petition.
(c) ''New dietary ingredient'' defined.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

351. Adulterated drugs and devices.
(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture.
(b) Strength, quality, or purity differing from official compendium.
(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium.

Sec.
(d) Mixture with or substitution of another substance.
(e) Devices not in conformity with performance standards.
(f) Certain class III devices.
(g) Banned devices.
(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions.
(i) Failure to comply with requirements under which device was exempted for investigational use.
352. Misbranded drugs and devices.
(a) False or misleading label.
(b) Package form; contents of label.
(c) Prominence of information on label.
(d) Habit forming substances.
(e) Designation of drugs or devices by established names.
(f) Directions for use and warnings on label.
(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug.
(h) Deteriorative drugs; packing and labeling.
(i) Drug; misleading container; imitation; offer for sale under another name.
(j) Health-endangering when used as prescribed.
(k) Insulin not properly certified.
(*l*) Antibiotic drugs improperly certified.
(m) Color additives; packing and labeling.
(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances.
(*o*) Drugs or devices from nonregistered establishments.
(p) Packaging or labeling of drugs in violation of regulations.
(q) Restricted devices using false or misleading advertising or used in violation of regulations.
(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter.
(s) Devices subject to performance standards not bearing requisite labeling.
(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information.
353. Exemptions and consideration for certain drugs, devices, and biological products.
(a) Regulations for goods to be processed, labeled, or repacked elsewhere.
(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws.
(c) Sales restrictions.
(d) Distribution of drug samples.
(e) Wholesale distributors; guidelines for licensing; definitions.
(f) Veterinary prescription drugs.
(g) Regulation of combination products.
354. Repealed.
355. New drugs.
(a) Necessity of effective approval of application.
Sec.
(b) Filing application; contents.
(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order.
(d) Grounds for refusing application; approval of application; ''substantial evidence'' defined.
(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health.
(f) Revocation of order refusing, withdrawing or suspending approval of application.
(g) Service of orders.
(h) Appeal from order.
(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary.
(j) Abbreviated new drug applications.
(k) Records and reports; required information; regulations and orders; access to records.
(*l*) Public disclosure of safety and effectiveness data.
(m) ''Patent'' defined.
356. Certification of drugs containing insulin.
(a) Standards for certification.
(b) Regulations.
(c) Tests or methods of assay; revision.
357. Certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug.
(a) Regulations prescribed by Secretary; release prior to certification; ''antibiotic drug'' defined.
(b) Provisions of regulations.
(c) Exemption of drugs not involving safety and efficacy of use; considerations; certification after exemption; labeling and advertising claims.
(d) Exemption of drugs stored, processed, and labeled at plants other than manufacturer's, used in manufacture of other drugs or for investigational purposes; discretionary and mandatory conditions; direct reports to Secretary.
(e) Exempted new drugs subject to section 355 of this title; request for certification of exempted drug; determination of compliance with sections 351(b) and 352(g) of this title.
(f) Filing of petitions; contents; notice; answer; public hearing; orders.
(g) Records and reports; professional ethics and interests of patients; examination of data; access to records.
(h) Issuance of regulations; conditions; amendment or repeal of regulations; effective date; procedure; lack of substantial evidence.
358. Authority to designate official names.
(a) Necessity or desirability; use in official compendiums; infringement of trademarks.
(b) Review of names in official compendiums.
(c) Determinations of complexity, usefulness, multiplicity, or lack of name; designation by Secretary.
(d) Revised official names; compilation, publication, and public distribution of listings.
(e) Request by compiler of official compendium for designation of name.
359. Nonapplicability of subchapter to cosmetics.

Sec.
360. Registration of producers of drugs or devices.
(a) Definitions.
(b) Annual registration.
(c) New producers.
(d) Additional establishments.
(e) Registration number; uniform system for identification of devices intended for human use.
(f) Availability of registrations for inspection.
(g) Exclusions from application of section.
(h) Inspection of premises.
(i) Foreign establishments.
(j) Filing of lists of drugs and devices manufactured, prepared, propagated and compounded by registrants; statements; accompanying disclosures.
(k) Report preceding introduction of devices into interstate commerce.
360a. Repealed.
360b. New animal drugs.
(a) Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research.
(b) Filing application for uses of new animal drug; contents; patent information; abbreviated application.
(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order; abbreviated applications; withdrawal periods; effective date of approval; relationship to other applications; withdrawal or suspension of approval; bioequivalence; filing of additional patent information.
(d) Grounds for refusing application; approval of application; factors; ''substantial evidence'' defined.
(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals.
(f) Revocation of order refusing, withdrawing or suspending approval of application.
(g) Service of orders.
(h) Appeal from order.
(i) Publication in Federal Register; effective date and revocation or suspension of regulation.
(j) Exemption of drugs for research; discretionary and mandatory conditions.
(k) Food containing new animal drug considered unadulterated while approval of application for such drug is effective.
(*l*) Records and reports; required information; regulations and orders; examination of data; access to records.
(m)(1) Filing application for uses of animal feed containing new animal drug; contents.
(2) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order.
(3) Grounds for refusing application; approval of application; approval effective during existence of subsection (i) regulation.
(4) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals.
(5) Records and reports; regulations and orders; access to records.
(n) Abbreviated applications for new animal drugs; contents, filing, etc.; lists of approved drugs.
(*o*) ''Patent'' defined.
(p) Safety and effectiveness data.
360c. Classification of devices intended for human use.
(a) Classes of devices.
(b) Classification panels.
(c) Classification panel organization and operation.
(d) Panel recommendation; publication; priorities.
(e) Classification changes.
(f) Initial classification and reclassification of certain devices.
(g) Information.
(h) Definitions.
(i) Substantial equivalence.
360d. Performance standards.
(a) Reasonable assurance of safe and effective performance; periodic evaluation.
(b) Establishment of a standard.
360e. Premarket approval.
(a) General requirement.
(b) Regulation to require premarket approval.
(c) Application for premarket approval.
(d) Action on application for premarket approval.
(e) Withdrawal and temporary suspension of approval of application.
(f) Product development protocol.
(g) Review.
(h) Service of orders.
(i) Revision.
360f. Banned devices.
(a) General rule.
(b) Special effective date.
360g. Judicial review.
(a) Petition; record.
(b) Additional data, views, and arguments.
(c) Standard for review.
(d) Finality of judgments.
(e) Remedies.
(f) Statement of reasons.
360h. Notification and other remedies.
(a) Notification.
(b) Repair, replacement, or refund.
(c) Reimbursement.
(d) Effect on other liability.
(e) Recall authority.
360i. Records and reports on devices.
(a) General rule.
(b) User reports.
(c) Persons exempt.
(d) Certification.
(e) Device tracking.
(f) Reports of removals and corrections.
360j. General provisions respecting control of devices intended for human use.
(a) General rule.
(b) Custom devices.
(c) Trade secrets.
(d) Notices and findings.
(e) Restricted devices.
(f) Good manufacturing practice requirements.
(g) Exemption for devices for investigational use.
(h) Release of information respecting safety and effectiveness.
(i) Proceedings of advisory panels and committees.
(j) Traceability.

Sec.
(k) Research and development.
(*l*) Transitional provisions for devices considered as new drugs or antibiotic drugs.
(m) Humanitarian device exemption.
360k. State and local requirements respecting devices.
(a) General rule.
(b) Exempt requirements.
360*l*. Postmarket surveillance.
(a) In general.
(b) Surveillance approval.

PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

360aa. Recommendations for investigations of drugs for rare diseases or conditions.
(a) Request by sponsor; response by Secretary.
(b) Regulations.
360bb. Designation of drugs for rare diseases or conditions.
(a) Request by sponsor; preconditions; ''rare disease or condition'' defined.
(b) Notification of discontinuance of drug or application as condition.
(c) Notice to public.
(d) Regulations.
360cc. Protection for drugs for rare diseases or conditions.
(a) Exclusive approval, certification, or license.
(b) Exceptions.
360dd. Open protocols for investigations of drugs for rare diseases or conditions.
360ee. Grants and contracts for development of drugs for rare diseases and conditions.
(a) Authority of Secretary.
(b) Definitions.
(c) Authorization of appropriations.

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

360hh. Definitions.
360ii. Program of control.
(a) Establishment.
(b) Powers of Secretary.
(c) Record keeping.
360jj. Studies by the Secretary.
(a) Report to Congress.
(b) Participation of other Federal agencies.
(c) Organization of studies and participation.
360kk. Performance standards for electronic products.
(a) Promulgation of regulations.
(b) Administrative procedure.
(c) Publication in Federal Register.
(d) Judicial review.
(e) Availability of record.
(f) Technical Electronic Product Radiation Safety Standards Committee.
(g) Review and evaluation.
(h) Product certification.
360*ll*. Notification of defects in and repair or replacement of electronic products.
(a) Notification; exemption.
(b) Method of notification.
(c) Requisite elements of notification.
(d) Copies to Secretary of communications by manufacturers to dealers or distributors regarding defects.
(e) Notice from Secretary to manufacturer of defects or failure to comply with standards.
(f) Correction of defects.
(g) Effective date.
360mm. Imports.
(a) Refusal of admission to noncomplying electronic products.
(b) Bond.
(c) Liability of owner or consignee for expenses connected with refusal of admission.
(d) Designation of agent for purposes of service.
360nn. Inspection, records, and reports.
(a) Inspection of premises.
(b) Record keeping.
(c) Disclosure of technical data.
(d) Public nature of reports.
(e) Trade secrets.
(f) Information required to identify and locate first purchasers of electronic products.
360*oo*. Prohibited acts.
360pp. Enforcement.
(a) Jurisdiction of courts.
(b) Penalties.
(c) Venue; process.
(d) Warnings.
(e) Compliance with regulations.
(f) Additional remedies.
360qq. Annual report.
360rr. Federal-State cooperation.
360ss. State standards.

SUBCHAPTER VI—COSMETICS

361. Adulterated cosmetics.
362. Misbranded cosmetics.
363. Regulations making exemptions.
364. Repealed.

SUBCHAPTER VII—GENERAL AUTHORITY

PART A—GENERAL ADMINISTRATIVE PROVISIONS

371. Regulations and hearings.
(a) Authority to promulgate regulations.
(b) Regulations for imports and exports.
(c) Conduct of hearings.
(d) Effectiveness of definitions and standards of identity.
(e) Procedure for establishment.
(f) Review of order.
(g) Copies of records of hearings.
372. Examinations and investigations.
(a) Authority to conduct.
(b) Availability to owner of part of analysis samples.
(c) Records of other departments and agencies.
(d) Information on patents for drugs.
(e) Powers of enforcement personnel.
372a. Transferred.
373. Records of interstate shipment.
374. Inspection.
(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions.
(b) Written report to owner; copy to Secretary.
(c) Receipt for samples taken.
(d) Analysis of samples furnished owner.
(e) Accessibility of records.
375. Publicity.
(a) Reports.
(b) Information regarding certain goods.
376. Examination of sea food on request of packer; marking food with results; fees; penalties.
377. Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests.
378. Advertising of foods.
(a) Determination of misbranding; notification of Federal Trade Commission by Secretary; contents.
(b) Action by Federal Trade Commission precluding action by Secretary; exception.

Sec.
(c) Secretary's determination of imminent hazard to health as suspending applicability of provisions.
(d) Coordination of action by Secretary with Federal Trade Commission.
379. Confidential information.
379a. Presumption of existence of jurisdiction.
379b. Consolidated administrative and laboratory facility.
(a) Authority.
(b) Awarding of contract.
(c) Donations.
(d) Authorization of appropriations.
379c. Transferred.
379d. Automation of Food and Drug Administration.
(a) In general.
(b) Authorization of appropriations.

PART B—COLORS

379e. Listing and certification of color additives for foods, drugs, devices, and cosmetics.
(a) Unsafe color additives.
(b) Listing of colors; regulations; issuance, amendment or repeal; referral to advisory committee; report and recommendations; appointment and compensation of advisory committee.
(c) Certification of colors.
(d) Procedure for issuance, amendment, or repeal of regulations.
(e) Fees.
(f) Exemptions.

PART C—FEES

SUBPART 1—FREEDOM OF INFORMATION FEES

379f. Recovery and retention of fees for freedom of information requests.
(a) In general.
(b) Use of fees.
(c) Waiver of fees.

SUBPART 2—FEES RELATING TO DRUGS

379g. Definitions.
379h. Authority to assess and use drug fees.
(a) Types of fees.
(b) Fee amounts.
(c) Increases and adjustments.
(d) Fee waiver or reduction.
(e) Effect of failure to pay fees.
(f) Assessment of fees.
(g) Crediting and availability of fees.
(h) Collection of unpaid fees.
(i) Construction.

SUBCHAPTER VIII—IMPORTS AND EXPORTS

381. Imports and exports.
(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission.
(b) Disposition of refused articles.
(c) Charges concerning refused articles.
(d) Reimportation.
(e) Exports.
382. Exports of certain unapproved products.
(a) Drugs intended for human or animal use which require approval or licensing.
(b) Conditions for export; active pursuit of drug approval or licensing; application for export, contents, approval or disapproval; list of eligible countries for export; criteria for list change.
(c) Report to Secretary by holder of approved application; events requiring report; annual report to Secretary on pursuit of approval of drug.
(d) Export of drug under approved application prohibited.
(e) Determination by Secretary of noncompliance, failure of active pursuit of drug approval, imminent hazard of drug to public health, or exportation of drug to noneligible country; notices and hearings; prohibition on exportation of drug.
(f) Drugs used in prevention or treatment of tropical disease.
(g) Reference to Secretary and holder of application.
383. Office of International Relations.

SUBCHAPTER IX—MISCELLANEOUS

391. Separability clause.
392. Exemption of meats and meat food products.
(a) Law determinative of exemption.
(b) Laws unaffected.
393. Food and Drug Administration.
(a) In general.
(b) Commissioner.
(c) Technical and scientific review groups.
394. Scientific review groups.
395. Loan repayment program.
(a) In general.
(b) Applicability of certain provisions.
(c) Authorization of appropriations.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 453, 457, 466, 467, 467f, 601, 607, 620, 679, 802, 811, 829, 902, 1033, 1049, 1052, 1401, 1402, 1403 of this title; title 7 sections 136v, 138i, 1431c, 5341, 6519; title 15 sections 70j, 1261, 1263, 1277, 1457, 1459, 1460, 2057a, 2057b, 2079; title 18 section 42; title 19 section 2578a; title 26 sections 170, 4817; title 35 sections 155, 156, 271; title 42 sections 262, 300aa–22, 300aa–23, 1396r–8, 1786, 3512, 7671.

## SUBCHAPTER I—SHORT TITLE

### § 301. Short title

This chapter may be cited as the Federal Food, Drug, and Cosmetic Act.

(June 25, 1938, ch. 675, § 1, 52 Stat. 1040.)

EFFECTIVE DATE; POSTPONEMENT IN CERTAIN CASES

Act June 23, 1939, ch. 242, §§ 1, 2, 53 Stat. 853, 854, provided that:

''[SEC. 1] (a) The effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402(c) [342(c) of this title]; 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k) of this title]; 501(a), (4) [351(a)(4) of this title]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; 601(e) [361(e) of this title]; and 602(b) [362(b) of this title].

''(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940 the effective date of the provisions of sections 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k)]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; and 602(b) [362(b) of this title] of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not

prevent the public interest being adequately served: Provided, That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

''SEC. 2. (a) The provisions of section 8 [section 10 of this title], paragraph fifth, under the heading 'In the case of food:', of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 [section 10 of this title] and of such regulations, shall remain in force until January 1, 1940.

''(b) The provisions of such Act of June 30, 1906, as amended, [sections 1 to 5, 7 to 15, and 372a of this title] to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act [section 343(k) of this title], shall remain in force until January 1, 1940.

''(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply—

''(1) to the provisions of section 502(d) and (e) of the Federal Food, Drug, and Cosmetic Act [352(d), (e) of this title], insofar as such provisions relate to any substance named in section 8 [section 10 of this title], paragraph second, under the heading 'In the case of drugs:', of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

''(2) to the provisions of section 502(b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act [352(b), (d) to (h) of this title], insofar as such provisions relate to drugs to which section 505 [355 of this title] of such Act applies.''

EFFECTIVE DATE

Section 902(a) of act June 25, 1938, provided that: ''This Act [enacting this chapter and repealing sections 1 to 5 and 7 to 15 of this title], shall take effect twelve months after the date of its enactment [June 25, 1938]. The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., 1934 ed., title 21, secs. 1–15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 [section 371 of this title] shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403(i) [section 343(i) of this title] for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401 [section 341 of this title]: *Provided further*, That sections 502(j), 505, and 601(a) [sections 352(j), 355, 361(a), respectively of this title], and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601(a) [section 361(a) of this title], relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 (U.S.C., 1934 ed., title 21, sec. 6 [section 321a of this title]; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U.S.C., 1934 ed., title 21, sec. 10 [section 321b of this title]; 41 Stat. 271, ch. 26], defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U.S.C. 1934 ed., Sup. III, title 21, sec. 14a [section 372a of this title]) shall remain in force and effect and be applicable to the provisions of this Act.''

HAZARDOUS SUBSTANCES

Federal Hazardous Substances Act as not modifying this chapter, see Pub. L. 86–613, § 18, July 12, 1960, 74 Stat. 380, set out as an Effect Upon Federal and State Laws note under section 1261 of Title 15, Commerce and Trade.

SHORT TITLE OF 1994 AMENDMENTS

Pub. L. 103–417, § 1(a), Oct. 25, 1994, 108 Stat. 4325, provided that: ''This Act [enacting sections 343–2 and 350b of this title and section 287c–11 of Title 42, The Public Health and Welfare, amending sections 321, 331, 342, 343, and 350 of this title and section 281 of Title 42, and enacting provisions set out as notes under sections 321 and 343 of this title] may be cited as the 'Dietary Supplement Health and Education Act of 1994'.''

Pub. L. 103–396, § 1, Oct. 22, 1994, 108 Stat. 4153, provided that: ''This Act [amending sections 331, 343–1, 360b, and 371 of this title and enacting provisions set out as notes under section 360b of this title] may be cited as the 'Animal Medicinal Drug Use Clarification Act of 1994'.''

SHORT TITLE OF 1993 AMENDMENT

Pub. L. 103–80, § 1, Aug. 13, 1993, 107 Stat. 773, provided that: ''This Act [amending sections 321, 331 to 333, 334, 335b, 341 to 343, 346a, 350a, 352, 355 to 358, 360b to 360e, 360i, 360cc, 360hh to 360ss, 361, 371, 372, 373, 374, 376, 379e, and 381 of this title and section 263b of Title 42, The Public Health and Welfare, and enacting provisions set out as a note under section 343 of this title] may be cited as the 'Nutrition Labeling and Education Act Amendments of 1993'.''

SHORT TITLE OF 1992 AMENDMENTS

Pub. L. 102–571, title I, § 101(a), Oct. 29, 1992, 106 Stat. 4491, provided that: ''This title [enacting sections 379g and 379h of this title, transferring sections 372a, 376, and 379c of this title to sections 376, 379e and 379f, respectively, of this title, amending sections 321, 331, 342, 343, 346a, 351, 352, 360j, 361, 362, 453, 601, and 1033 of this title, enacting provisions set out as notes under section 379g of this title, and amending provisions set out as notes under sections 343 and 343–1 of this title] may be cited as the 'Prescription Drug User Fee Act of 1992'.''

Pub. L. 102–571, title II, § 201, Oct. 29, 1992, 106 Stat. 4500, provided that: ''This title [enacting provisions set out as notes under sections 343 and 393 of this title and amending provisions set out as notes under sections 343 and 343–1 of this title] may be cited as the 'Dietary Supplement Act of 1992'.''

Pub. L. 102–353, § 1(a), Aug. 26, 1992, 106 Stat. 941, provided that: ''This Act [amending sections 333, 353, and 381 of this title and enacting provisions set out as a note under section 353 of this title] may be cited as the 'Prescription Drug Amendments of 1992'.''

Pub. L. 102–300, § 1(a), June 16, 1992, 106 Stat. 238, provided that: ''This Act [amending sections 321, 331, 334, 346a, 352, 353, 356, 357, 360c, 360d, 360g to 360i, 360*l*, 360mm, 371 to 372a, 376, and 381 of this title and section 262 of Title 42, The Public Health and Welfare and enacting and amending provisions set out as notes under section 360i of this title] may be cited as the 'Medical Device Amendments of 1992'.''

Pub. L. 102–282, § 1(a), May 13, 1992, 106 Stat. 149, provided that: ''This Act [enacting sections 335a to 335c of this title, amending sections 321, 336, 337, and 355 of this title, and enacting provisions set out as notes under section 335a of this title] may be cited as the 'Generic Drug Enforcement Act of 1992'.''

SHORT TITLE OF 1990 AMENDMENTS

Pub. L. 101–635, § 1(a), Nov. 28, 1990, 104 Stat. 4583, provided that: ''This Act [enacting sections 379b to 379d and 394 of this title] may be cited as the 'Food and Drug Administration Revitalization Act'.''

Pub. L. 101–629, § 1(a), Nov. 28, 1990, 104 Stat. 4511, provided that: ''This Act [enacting sections 360*l* and 383 of

this title, amending sections 321, 333, 351, 353, and 360c to 360j of this title and sections 263b to 263n of Title 42, The Public Health and Welfare, redesignating sections 263b to 263n of Title 42 as sections 360gg to 360ss of this title, repealing section 263b of Title 42, and enacting provisions set out as notes under sections 333, 360c, 360i, 360j, 360hh and 383 of this title] may be cited as the 'Safe Medical Devices Act of 1990'.''

Pub. L. 101–535, §1(a), Nov. 8, 1990, 104 Stat. 2353, provided that: ''This Act [enacting section 343–1 of this title, amending sections 321, 337, 343, 345, and 371 of this title, and enacting provisions set out as notes under sections 343 and 343–1 of this title] may be cited as the 'Nutrition Labeling and Education Act of 1990'.''

SHORT TITLE OF 1988 AMENDMENTS

Pub. L. 100–670, §1(a), Nov. 16, 1988, 102 Stat. 3971, provided that: ''This Act [amending sections 321, 353, and 360b of this title, section 2201 of Title 28, Judiciary and Judicial Procedure, and sections 156 and 271 of Title 35, Patents, and enacting provisions set out as notes under section 360b of this title] may be cited as the 'Generic Animal Drug and Patent Term Restoration Act'.''

Pub. L. 100–607, title V, §501, Nov. 4, 1988, 102 Stat. 3120, provided that: ''This title [enacting section 393 of this title, amending sections 5315 and 5316 of Title 5, Government Organization and Employees, and enacting provisions set out as notes under section 393 of this title] may be cited as the 'Food and Drug Administration Act of 1988'.''

Pub. L. 100–293, §1(a), Apr. 22, 1988, 102 Stat. 95, provided that: ''This Act [amending sections 331, 333, 353, and 381 of this title and enacting provisions set out as notes under section 353 of this title] may be cited as the 'Prescription Drug Marketing Act of 1987'.''

Pub. L. 100–290, §1, Apr. 18, 1988, 102 Stat. 90, provided that: ''This Act [amending sections 360bb and 360ee of this title, enacting provisions set out as a note under section 360aa of this title, and amending provisions set out as a note under section 236 of Title 42, The Public Health and Welfare] may be cited as the 'Orphan Drug Amendments of 1988'.''

SHORT TITLE OF 1986 AMENDMENT

Pub. L. 99–660, title I, §101(a), Nov. 14, 1986, 100 Stat. 3743, provided that: ''This title [enacting section 382 of this title, amending sections 241 and 262 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under section 333 of this title and section 262 of Title 42] may be cited as the 'Drug Export Amendments Act of 1986'.''

SHORT TITLE OF 1985 AMENDMENT

Pub. L. 99–91, §1, Aug. 15, 1985, 99 Stat. 387, provided that: ''This Act [amending sections 360aa to 360cc, and 360ee of this title, and sections 295g–1 and 6022 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under section 360aa of this title and section 236 of Title 42] may be cited as the 'Orphan Drug Amendments of 1985'.''

SHORT TITLE OF 1984 AMENDMENT

Pub. L. 98–417, §1, Sept. 24, 1984, 98 Stat. 1585, provided: ''That this Act [enacting section 156 of Title 35, Patents, amending sections 355 and 360cc of this title, sections 68b, 68c, and 70b of Title 15, Commerce and Trade, section 2201 of Title 28, Judiciary and Judicial Procedure, and sections 271 and 282 of Title 35, and enacting provisions set out as notes under section 355 of this title and section 68b of Title 15] may be cited as the 'Drug Price Competition and Patent Term Restoration Act of 1984'.''

SHORT TITLE OF 1983 AMENDMENTS

Pub. L. 98–22, §1, Apr. 22, 1983, 97 Stat. 173, provided: ''That this Act [amending provisions set out as a note under section 348 of this title] may be cited as the 'Saccharin Study and Labeling Act Amendment of 1983'.''

Pub. L. 97–414, §1(a), Jan. 4, 1983, 96 Stat. 2049, provided that: ''This Act [enacting part B of subchapter V of chapter 9 of this title, section 44H of Title 26, Internal Revenue Code, section 155 of Title 35, Patents, and sections 236, 255, and 298b–4 of Title 42, The Public Health and Welfare, amending sections 1274, 1472, 2055, 2060, 2064, 2068, and 2080 of Title 15, Commerce and Trade, section 904 of this title, sections 280C and 6096 of Title 26, and sections 209, 231, 242k, 242m, 243, 254c, 254j, 254m, 254*o*, 254p, 256, 294j, 295g–1, 295g–4, 295h, 295h–1a, 297–1, 300, 300a–1, 300a–3, 300b, 300e–1, 300m, 300n–5, 300q–2, 300u–5, 300w–3, 300x–1, 300x–4, 300y–11, 4577, and 4588 of Title 42, enacting provisions set out as notes under section 360aa of this title, section 44H of Title 26, and sections 241, 255, 287i, and 300x–1 of Title 42, and repealing provisions set out as a note under section 300t–11 of Title 42] may be cited as the 'Orphan Drug Act'.''

SHORT TITLE OF 1981 AMENDMENT

Pub. L. 97–42, §1, Aug. 14, 1981, 95 Stat. 946, provided: ''That this Act [amending provisions set out as a note under section 348 of this title] may be cited as the 'Saccharin Study and Labeling Act Amendment of 1981'.''

SHORT TITLE OF 1980 AMENDMENT

Pub. L. 96–359, §1, Sept. 26, 1980, 94 Stat. 1190, provided: ''That this Act [enacting section 350a of this title, amending sections 321, 331, 374, 830, 841 to 843, and 873 of this title, and enacting a provision set out as a note under section 350a of this title] may be cited as the 'Infant Formula Act of 1980'.''

SHORT TITLE OF 1977 AMENDMENT

Pub. L. 95–203, §1, Nov. 23, 1977, 91 Stat. 1451, provided that: ''This Act [enacting section 343a of this title, amending sections 321 and 343 of this title, enacting provisions set out as notes under sections 343 and 348 of this title, and amending provisions set out as notes under sections 218 and 289*l*–1 of Title 42, The Public Health and Welfare] may be cited as the 'Saccharin Study and Labeling Act'.''

SHORT TITLE OF 1976 AMENDMENT

Pub. L. 94–295, §1(a), May 28, 1976, 90 Stat. 539, provided that: ''This Act [enacting sections 360c to 360k, 379, and 379a of this title and section 3512 of Title 42, The Public Health and Welfare, and amending sections 321, 331, 334, 351, 352, 358, 360, 374, 379e, and 381 of this title and section 55 of Title 15, Commerce and Trade] may be cited as the 'Medical Device Amendments of 1976'.''

SHORT TITLE OF 1972 AMENDMENT

Pub. L. 92–387, §1, Aug. 16, 1972, 86 Stat. 559, provided that: ''This Act [amending sections 331, 335, and 360 of this title and enacting provisions set out as notes under section 360 of this title] may be cited as the 'Drug Listing Act of 1972'.''

SHORT TITLE OF 1968 AMENDMENTS

Pub. L. 90–602, §1, Oct. 18, 1968, 82 Stat. 1173, provided that: ''This Act [enacting provisions now comprising part C (§§360hh–360ss) of subchapter III of this chapter and provisions set out as notes under section 360hh of this title] may be cited as the 'Radiation Control for Health and Safety Act of 1968'.''

Pub. L. 90–399, §1, July 13, 1968, 82 Stat. 342, provided: ''That this Act [enacting section 360b of this title, amending sections 321, 331, 342, 351, 352, 357, 381, and 392 of this title, and enacting provisions set out as a note under section 360b of this title] may be cited as the 'Animal Drug Amendments of 1968'.''

SHORT TITLE OF 1965 AMENDMENT

Pub. L. 89–74, §1, July 15, 1965, 79 Stat. 226, provided: ''That this Act [amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321 and 352 of this title]

may be cited as the 'Drug Abuse Control Amendments of 1965'.''

SHORT TITLE OF 1962 AMENDMENT

Pub. L. 87–781, §1, Oct. 10, 1962, 76 Stat. 780, provided in part that such Act [enacting sections 358 to 360 of this title, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 379e, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 358, 360, and 374 of this title] may be cited as the 'Drug Amendments of 1962'.''

SHORT TITLE OF 1960 AMENDMENT

Pub. L. 86–618, §1, July 12, 1960, 74 Stat. 397, provided: ''That this Act [amending sections 321, 331, 333, 342, 346, 351, 352, 361, 362, 371, and 379e of this title, repealing sections 354 and 364 of this title, and enacting notes set out under this section] may be cited as the 'Color Additive Amendments of 1960'.''

SHORT TITLE OF 1958 AMENDMENT

Pub. L. 85–929, §1, Sept. 6, 1958, 72 Stat. 1784, provided: ''That this Act [amending sections 321, 331, 342, 346, 348 of this title and section 210 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 321, 342, and 451 of this title] may be cited as the 'Food Additives Amendment of 1958'.''

## SUBCHAPTER II—DEFINITIONS

### § 321. Definitions; generally

For the purposes of this chapter—

(a)(1) The term ''State'', except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term ''Territory'' means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term ''interstate commerce'' means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term ''Department'' means Department of Health and Human Services.

(d) The term ''Secretary'' means the Secretary of Health and Human Services.

(e) The term ''person'' includes individual, partnership, corporation, and association.

(f) The term ''food'' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term ''drug'' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term ''counterfeit drugs'' means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term ''device'' (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term ''cosmetic'' means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term ''official compendium'' means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term ''label'' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(*l*) The term ''immediate container'' does not include package liners.

(m) The term ''labeling'' means all labels and other written, printed, or graphic matter (1)

upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(*o*) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term ''new drug'' means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a ''new drug'' if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term ''pesticide chemical'' means any substance which, alone, in chemical combination or in formulation with one or more other substances, is ''a pesticide'' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term ''raw agricultural commodity'' means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term ''food additive'' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term ''color additive'' means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term ''color'' includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term ''safe'' as used in paragraph (s) of this section and in sections 348, 360b, and 379e of this title, has reference to the health of man or animal.

(v) The term ''new animal drug'' means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a ''new animal drug'' if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(w) The term ''animal feed'', as used in paragraph (w)[1] of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term ''informal hearing'' means a hearing which is not subject to section 554, 556, or 557 of title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term ''saccharin'' includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term ''infant formula'' means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term ''abbreviated drug application'' means an application submitted under section 355(j) or 357 of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(bb) The term ''knowingly'' or ''knew'' means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 335a of this title, the term ''high managerial agent''—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 335a and 335b of this title, the term ''drug product'' means a drug subject to regulation under section 355, 357, 360b, or 382 of this title or under section 262 of title 42.

(ee) The term ''Commissioner'' means the Commissioner of Food and Drugs.

(ff) The term ''dietary supplement''—

(1) means a product (other than tobacco) intended to supplement the diet that bears or

[1] So in original. Probably should be paragraph ''(v)''.

contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include—

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of paragraph (g), a dietary supplement shall be deemed to be a food within the meaning of this chapter.

(June 25, 1938, ch. 675, §201, 52 Stat. 1040; July 22, 1954, ch. 559, §1, 68 Stat. 511; Sept. 6, 1958, Pub. L. 85–929, §2, 72 Stat. 1784; July 12, 1960, Pub. L. 86–618, title I, §101, 74 Stat. 397; Oct. 10, 1962, Pub. L. 87–781, title I, §102(a), title III, §307(a), 76 Stat. 781, 796; July 15, 1965, Pub. L. 89–74, §§3(a), 9(b), 79 Stat. 227, 234; July 13, 1968, Pub. L. 90–399, §102, 82 Stat. 351; Oct. 24, 1968, Pub. L. 90–639, §§1, 4(a), 82 Stat. 1361, 1362; Oct. 27, 1970, Pub. L. 91–513, title II, §701(a), (g), 84 Stat. 1281, 1282; Oct. 21, 1972, Pub. L. 92–516, §3(3), 86 Stat. 998; Apr. 22, 1976, Pub. L. 94–278, title V, §502(a)(2)(A), 90 Stat. 411; May 28, 1976, Pub. L. 94–295, §3(a)(1)(A), (2), 90 Stat. 575; Nov. 23, 1977, Pub. L. 95–203, §4(b)(3), 91 Stat. 1453; Sept. 26, 1980, Pub. L. 96–359, §3, 94 Stat. 1193; Nov. 16, 1988, Pub. L. 100–670, title I, §107(a)(1), 102 Stat. 3984; Nov. 8, 1990, Pub. L. 101–535, §5(b), 104 Stat. 2362; Nov. 28, 1990, Pub. L. 101–629, §16(b), 104 Stat. 4526; May 13, 1992, Pub. L. 102–282, §6, 106 Stat. 161; June 16, 1992, Pub. L. 102–300, §6(a), (b), 106 Stat. 240; Oct. 29, 1992, Pub. L. 102–571, title I, §107(1), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103–80, §§3(b), (dd)(1), 4(b), 107 Stat. 775, 779; Oct. 25, 1994, Pub. L. 103–417, §§3(a), (b), 10(a), 108 Stat. 4327, 4332.)

REFERENCES IN TEXT

The Food and Drugs Act of June 30, 1906, as amended, referred to in par. (p)(1), and the Food and Drug Act of June 30, 1906, as amended, referred to in par. (v)(1), is act June 30, 1906, ch. 3915, 34 Stat. 768, as amended, which was classified to subchapter I (§1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 372a of this title) by act June 25, 1938, ch. 675, §902(a), 52 Stat. 1059, and is covered by this chapter.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in par. (q), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Poultry Products Inspection Act, referred to in par. (s)(4), is Pub. L. 85–172, Aug. 28, 1957, 71 Stat. 441, as amended, which is classified generally to chapter 10 (§451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables.

The Meat Inspection Act of March 4, 1907, as amended and extended, referred to in par. (s)(4), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90–201, 81 Stat. 584, which are classified generally to subchapters I to IV (§601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

AMENDMENTS

1994—Par. (g)(1). Pub. L. 103–417, §10(a), amended last sentence generally. Prior to amendment, last sentence read as follows: "A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling contains such a claim."

Par. (s)(6). Pub. L. 103–417, §3(b), added subpar. (6).

Par. (ff). Pub. L. 103–417, §3(a), added par. (ff).

1993—Pars. (c), (d). Pub. L. 103–80, §3(dd)(1), substituted "Health and Human Services" for "Agriculture".

Par. (h). Pub. L. 103–80, §4(b), amended directory language of Pub. L. 102–300, §6(a)(1). See 1992 amendment note below.

Pars. (v) to (ff). Pub. L. 103–80, §3(b), redesignated pars. (w) to (ff) as (v) to (ee), respectively.

1992—Pars. (c), (d). Pub. L. 102–300, §6(b)(1), which directed the substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions notes below.

Par. (h). Pub. L. 102–300, §6(a)(1), as amended by Pub. L. 103–80, §4(b), substituted "its primary" for "any of its principal" in two places in concluding provisions.

Par. (u). Pub. L. 102–571 substituted ''379e'' for ''376''.

Par. (y)(1). Pub. L. 102–300, § 6(b)(2), struck out ''of Health, Education, and Welfare'' after ''employees of the Department''.

Pars. (bb) to (ee). Pub. L. 102–282 added pars. (bb) to (ee).

Par. (ff). Pub. L. 102–300, § 6(a)(2), added par. (ff).

1990—Par. (g)(1). Pub. L. 101–629, § 16(b)(1), struck out ''; but does not include devices or their components, parts, or accessories'' after ''clause (A), (B), or (C)''.

Pub. L. 101–535 inserted at end ''A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling contains such a claim.''

Par. (h)(3). Pub. L. 101–629, § 16(b)(2), which directed the amendment of subpar. (3) by substituting ''its primary'' for ''any of its principal'', could not be executed because ''any of its principal'' did not appear in subpar. (3).

1988—Par. (w)(3). Pub. L. 100–670 struck out subpar. (3) which read as follows: ''which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug.''

1980—Par. (aa). Pub. L. 96–359 added par. (aa).

1977—Par. (z). Pub. L. 95–203 added par. (z).

1976—Par. (h). Pub. L. 94–295, § 3(a)(1)(A), expanded definition of ''device'' to include implements, machines, implants, in vitro reagents, and other similar or related articles, added recognition in the National Formulary or the United States Pharmacopeia, or any supplement to the Formulary or Pharmacopeia, to the enumeration of conditions under which a device may qualify for inclusion under this chapter, and inserted requirements that a device be one which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Par. (n). Pub. L. 94–278 inserted ''or advertising'' after ''labeling'' wherever appearing.

Par. (y). Pub. L. 94–295, § 3(a)(2), added par. (y).

1972—Par. (q). Pub. L. 92–516 substituted reference to pesticide for reference to economic poison.

1970—Par. (a)(2). Pub. L. 91–513, § 701(g), struck out reference to sections 321, 331(i), 331(p), 331(q), 332, 333, 334, 337, 360, 360a, 372, 373, 374, and 375 of this title as they apply to depressant or stimulant drugs.

Par. (v). Pub. L. 91–513, § 701(a), struck out par. (v) which defined ''depressant or stimulant drug''.

1968—Par. (a)(2). Pub. L. 90–639, § 4(a), extended provisions to cover depressant and stimulant drugs, the containers thereof, and equipment used in manufacturing, compounding, or processing such drugs, to the Canal Zone.

Par. (p). Pub. L. 90–399, § 102(a), (b), inserted ''(except a new animal drug or an animal feed bearing or containing a new animal drug)'' after ''Any drug'' in subpars. (1) and (2), respectively.

Par. (s)(5). Pub. L. 90–399, § 102(c), added subpar. (5).

Par. (u). Pub. L. 90–399, § 102(d), inserted reference to section 360b of this title.

Par. (v)(3). Pub. L. 90–639, § 1, inserted reference to lysergic acid diethylamide.

Pars. (w), (x). Pub. L. 90–399, § 102(e), added pars. (w) and (x).

1965—Par. (g). Pub. L. 89–74, § 9(b), designated existing provisions as subpar. (1), redesignated cls. (1) to (4) thereof as (A) to (D), substituted ''(A), (B), or (C)'' for ''(1), (2), or (3)'' and added subpar. (2).

Par. (v). Pub. L. 89–74, § 3(a), added par. (v).

1962—Par. (a). Pub. L. 87–781, § 307(a), designated existing provisions as subpar. (2), inserted ''Commonwealth of Puerto Rico and the'', and added subpar. (1).

Par. (p)(1). Pub. L. 87–781, § 102(a)(1), inserted ''and effectiveness'' after ''to evaluate the safety'', and ''and effective'' after ''as safe''.

Par. (p)(2). Pub. L. 87–781, § 102(a)(2), inserted ''and effectiveness'' after ''safety''.

1960—Par. (s). Pub. L. 86–618, § 101(a), excluded color additives from definition of ''food additive''.

Par. (t). Pub. L. 86–618, § 101(c), added par. (t). Former par. (t) redesignated (u).

Par. (u). Pub. L. 86–618, § 101(b), redesignated par. (t) as (u) and inserted reference to section 376 of this title.

1958—Pars. (s), (t). Pub. L. 85–929 added pars. (s) and (t).

1954—Pars. (q), (r). Act July 22, 1954, added pars. (q) and (r).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101–535, set out as a note under section 343 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94–278, set out as a note under section 334 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–516 effective at the close of Oct. 21, 1972, except if regulations are necessary for the implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92–516, and regulations thereunder, see section 4 of Pub. L. 92–516, set out as an Effective Date note under section 136 of Title 7, Agriculture.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS; TRANSITIONAL PROVISIONS

Section 6 of Pub. L. 90–639 provided that: ''The amendments made by this Act [amending this section, sections 331, 333, 334, and 360a of this title, and provisions set out as a note under section 289a of Title 42, The Public Health and Welfare] shall apply only with respect to violations of the Federal Food, Drug, and Cosmetic Act [this chapter] committed after the date of the enactment of this Act [Oct. 24, 1968].''

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, except that in the case of a drug (other than one subject to section 360b(n) of this title) intended for use in animals other than man which, on Oct. 9, 1962, was commercially used or sold in the United States, was not a new drug as defined in par. (p) of this section then in force, and was not covered by an effective application under section 355 of this title, the words ''effectiveness'' and ''effective'' contained in par. (w) of this section not applicable to such drug when intended solely for use

under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day, see section 108(a), (b)(3) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Section 11 of Pub. L. 89–74 provided that: ''The foregoing provisions of this Act [see Short Title of 1965 Amendment note set out under section 301 of this title] shall take effect on the first day of the seventh calendar month [Feb. 1, 1966] following the month in which this Act is enacted [July 15, 1965]; except that (1) the Secretary shall permit persons, owning or operating any establishment engaged in manufacturing, preparing, propagating, compounding, processing, wholesaling, jobbing, or distributing any depressant or stimulant drug, as referred to in the amendments made by section 4 of this Act to section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title], to register their name, places of business, and establishments, and other information prescribed by such amendments, with the Secretary prior to such effective date, and (2) sections 201(v) and 511(g) of the Federal Food, Drug, and Cosmetic Act, as added by this act [par. (v) of this section and par. (g) of section 360a of this title], and the provisions of sections 8 [amending section 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure] and 10 [set out as a note under this section] shall take effect upon the date of enactment of this Act [July 15, 1965].''

EFFECTIVE DATE OF 1962 AMENDMENT

Section 107 of Pub. L. 87–781 provided that:

''(a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A [amending this section and sections 331, 332, 348, 351 to 353, 355, 357, 379e of this title, and enacting provisions set out as a note under section 355 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962].

''(b) The amendments made by sections 101, 103, 105, and 106 of this part A [amending sections 331, 332, 351, 352, 355, and 357 of this title] shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted [Oct. 1962].

''(c)(1) As used in this subsection, the term 'enactment date' means the date of enactment of this Act; and the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter].

''(2) An application filed pursuant to section 505(b) of the basic Act [section 355(b) of this title] which was 'effective' within the meaning of that Act on the day immediately preceding the enactment date shall be deemed as of the enactment date, to be an application 'approved' by the Secretary within the meaning of the basic Act as amended by this Act.

''(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection—

''(A) the amendments made by this Act to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act [par. (p) of this section, and subsecs. (b) and (d) of section 355 of this title], insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act [section 355(e) of this title], apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

''(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act [section 355(e) of this title], shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act [section 355 of this title]) until whichever of the following first occurs: (i) the expiration of the two-year period beginning with the enactment date; (ii) the effective date of an order under section 505(e) of the basic Act [section 355(e) of this title], other than clause (3) of the first sentence of such section 505(e) [section 355(e) of this title], withdrawing or suspending the approval of such application.

''(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force [par. (p) of this section], and (C) was not covered by an effective application under section 505 of that Act [section 355 of this title], the amendments to section 201(p) [par. (p) of this section] made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.''

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF 1958 AMENDMENT

Amendment by Pub. L. 85–929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1954 AMENDMENT

For effective date of amendment by act July 22, 1954, see section 5 of that act, set out as a note under section 342 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 102–282

Amendment by Pub. L. 102–282 not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102–282, see section 7 of Pub. L. 102–282, set out as a note under section 335a of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101–535

Amendments by Pub. L. 101–535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101–535, set out as a note under section 343 of this title.

SAVINGS PROVISION

Section 702 of Pub. L. 91–513, as amended by Pub. L. 93–481, § 2, Oct. 26, 1974, 88 Stat. 1455, provided that:

''(a) Prosecutions for any violation of law occurring prior to the effective date [see Effective Date of 1970 Amendment note above] of section 701 [repealing section 360a of this title, and amending sections 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114 and 1952 of Title 18, Crimes and Criminal Procedure, and section 242 of Title 42, The Public Health and Welfare]

shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

''(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

''(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on the date of enactment of this Act [Oct. 27, 1970] shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act [par. (v) of this section], such drug shall automatically be controlled under this title [subchapter I of chapter 13 of this title] by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 [section 812 of this title] within schedules I through V shall automatically be controlled under this title [subchapter I of chapter 13 of this title] by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary.

''(d) Notwithstanding subsection (a) of this section or section 1103 [of Pub. L. 91–513, set out as a note under sections 171 to 174 of this title], section 4202 of title 18, United States Code, shall apply to any individual convicted under any of the laws repealed by this title or title III [subchapter I or subchapter II of chapter 13 of this title] without regard to the terms of any sentence imposed on such individual under such law.''

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

Functions of Secretary of Health, Education, and Welfare [now Health and Human Services] under Federal Food, Drug, and Cosmetic Act, to the extent such functions related to administration and enforcement of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), transferred to Consumer Product Safety Commission by section 2079 of Title 15, Commerce and Trade.

Functions of Secretary of Health, Education, and Welfare [now Health and Human Services] under Drug Abuse Control Amendments of 1965 [see Short Title of 1965 Amendment note set out under section 301 of this title] transferred to Attorney General except function of regulating counterfeiting of those drugs which are not ''depressant or stimulant'' drugs, see section 2 of Reorg. Plan No. 1 of 1968, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

CONGRESSIONAL FINDINGS RELATING TO PUB. L. 103–417

Section 2 of Pub. L. 103–417 provided that: ''Congress finds that—

''(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

''(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

''(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

''(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

''(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

''(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

''(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

''(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well-being of the country;

''(7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;

''(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

''(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

''(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

''(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

''(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

''(B) the industry consistently projects a positive trade balance; and

''(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;

''(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

''(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

''(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

''(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements.''

DISSEMINATION OF INFORMATION REGARDING THE DANGERS OF DRUG ABUSE

Section 5 of Pub. L. 90–639 provided that: ''It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, the highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse.''

CONGRESSIONAL FINDINGS AND DECLARATION OF POLICY

Section 2 of Pub. L. 89–74 provided that: ''The Congress hereby finds and declares that there is a widespread illicit traffic in depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act [see Short Title of 1965 Amendment note set out under section 301 of this title], would discriminate against and adversely affect interstate commerce in such drugs.''

EFFECT OF DRUG ABUSE CONTROL AMENDMENTS OF 1965 ON STATE LAWS

Section 10 of Pub. L. 89–74 provided that:

''(a) Nothing in this Act [enacting section 360a of this title, amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321, 352, and 360a of this title] shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State in contravention of the laws of such State.

''(b) No provision of this Act nor any amendment made by it shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, unless there is a direct and positive conflict between such provision or amendment and such State law so that the two cannot be reconciled or consistently stand together.

''(c) No amendment made by this Act shall be construed to prevent the enforcement in the courts of any State of any statute of such State prescribing any criminal penalty for any act made criminal by any such amendment.''

EFFECT OF DRUG AMENDMENTS OF 1962 ON STATE LAWS

Section 202 of Pub. L. 87–781 provided that: ''Nothing in the amendments made by this Act [enacting sections 358 to 360, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 379e, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 360, and 374 of this title] to the Federal Food, Drug, and Cosmetic Act [this chapter] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.''

CROSS REFERENCES

Appropriations for purpose and administration of pars. (q) and (r) of this section, see section 346b of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 343, 346b, 350, 352, 355, 360b, 379e, 802, 825 of this title; title 7 section 136; title 15 sections 1454, 1456, 1471, 2052, 2602; title 18 sections 842, 1365; title 35 section 156; title 42 sections 274e, 287c–11, 289g–2, 300cc–12, 1396r–8; title 49 section 5702.

## § 321a. "Butter" defined

For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) ''butter'' shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

(Mar. 4, 1923, ch. 268, 42 Stat. 1500.)

REFERENCES IN TEXT

The Food and Drug Act of June 30, 1906, referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, as amended, which was classified to subchapter I (§1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059, and is covered by this chapter.

CODIFICATION

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to section 6 of this title. Section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

## § 321b. "Package" defined

The word ''package'' where it occurs the second and last time in the act entitled ''An act to amend section 8 of an act entitled, 'An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,' '' approved March 3, 1913, shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.

(July 24, 1919, ch. 26, 41 Stat. 271.)

REFERENCES IN TEXT

An act approved March 3, 1913, referred to in text, is act Mar. 3, 1913, ch. 117, 37 Stat. 732, which amended section 10 of this title. For complete classification of this Act to the Code, see Tables.

''An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,'', referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, which was classified to subchapter I (§1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059, and is covered by this chapter.

CODIFICATION

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to the last sentence of paragraph third of section 10 of this title. Section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

## § 321c. Nonfat dry milk; "milk" defined

For the purposes of the Federal Food, Drug, and Cosmetic Act of June 26, 1938, (ch. 675, sec.

1, 52 Stat. 1040) [21 U.S.C. 301 et seq.] nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.

The term ''milk'', when used herein, means sweet milk of cows.

(Mar. 2, 1944, ch. 77, 58 Stat. 108; July 2, 1956, ch. 495, 70 Stat. 486.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act of June 26, 1938 (ch. 675, sec. 1, 52 Stat. 1040), referred to in text, probably means act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter (§ 301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, but was made applicable thereto.

AMENDMENTS

1956—Act July 2, 1956, substituted ''nonfat dry milk'' for ''nonfat dry milk solids or defatted milk solids''.

## SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 378 of this title; title 15 section 1456.

### § 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a or 373 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 355(i) or (k), 357(d) or (g), 360b(a)(4)(C), 360b(j), (*l*), or (m), 360e(f), or 360i of this title, or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344, 356, 357, or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 355, 356, 357, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 374, 379, or 379e of this title concerning any method or process which as a trade secret is entitled to protection. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(*l*) The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 355, 360e, or 360j(g) of this title, as the case may be, or that such drug or device complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(*o*) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or dis-

tributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) or 360(k) of this title, or the failure to provide a notice required by section 360(j)(2) of this title.

(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360j(g) of this title, (B) furnish any notification or other material or information required by or under section 360i or 360j(g) of this title, or (C) comply with a requirement under section 360*l* of this title.

(2) With respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, or the distribution of drugs in violation of section 353(e) of this title or the failure to otherwise comply with the requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

(u)[1] The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(June 25, 1938, ch. 675, §301, 52 Stat. 1042; Dec. 22, 1941, ch. 613, §1, 55 Stat. 851; July 6, 1945, ch. 281, §1, 59 Stat. 463; Mar. 10, 1947, ch. 16, §1, 61 Stat. 11; June 24, 1948, ch. 613, §1, 62 Stat. 582; Mar. 16, 1950, ch. 61, §3(b), 64 Stat. 20; Aug. 7, 1953, ch. 350, §2, 67 Stat. 477; Sept. 6, 1958, Pub. L. 85–929, §5, 72 Stat. 1788; July 12, 1960, Pub. L. 86–618, title I, §§104, 105(a), 74 Stat. 403; Oct. 10, 1962, Pub. L. 87–781, title I, §§103(c), 104(e)(1), 106(c), 114(a), title III, §304, 76 Stat. 784, 785, 788, 791, 795; July 15, 1965, Pub. L. 89–74, §§5, 9(c), 79 Stat. 232, 235; July 13, 1968, Pub. L. 90–399, §103, 82 Stat. 352; Oct. 24, 1968, Pub. L. 90–639, §2(b), 82 Stat. 1361; Oct. 27, 1970, Pub. L. 91–513, title II, §701(a), 84 Stat. 1281; Aug. 16, 1972, Pub. L. 92–387, §4(e), 86 Stat. 562; May 28, 1976, Pub. L. 94–295, §§3(b), 4(b)(1), 7(b), 90 Stat. 576, 580, 582; Sept. 26, 1980, Pub. L. 96–359, §5, 94 Stat. 1193; Oct. 27, 1986, Pub. L. 99–570, title IV, §4014(b)(2), 100 Stat. 3207–120; Apr. 22, 1988, Pub. L. 100–293, §7(a), 102 Stat. 99; Nov. 3, 1990, Pub. L. 101–502, §5(j), 104 Stat. 1289; Nov. 5, 1990, Pub. L. 101–508, title IV, §4755(c)(2), 104 Stat. 1388–210; June 16, 1992, Pub. L. 102–300, §3(a)(1), 106 Stat. 238; Oct. 29, 1992, Pub. L. 102–571, title I, §107(2), (3), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103–80, §3(c), 107 Stat. 775; Oct. 22, 1994, Pub. L. 103–396, §2(b)(1), 108 Stat. 4154; Oct. 25, 1994, Pub. L. 103–417, §10(b), 108 Stat. 4332.)

AMENDMENTS

1994—Par. (e). Pub. L. 103–396, §2(b)(1)(A), substituted ''357(d) or (g), 360b(a)(4)(C),'' for ''357(d) or (g),''.

Par. (u). Pub. L. 103–417 added par. (u) relating to introduction into interstate commerce of unsafe dietary supplement.

Pub. L. 103–396, §2(b)(1)(B), added par. (u) relating to failure to comply with regulations or orders of Secretary.

1993—Par. (j). Pub. L. 103–80, §3(c)(1), substituted ''379, or 379e'' for ''379e, or 379''.

Par. (s). Pub. L. 103–80, §3(c)(2), substituted ''350a(e)'' for ''350a(d)''.

1992—Pars. (i)(1), (j). Pub. L. 102–571 substituted ''379e'' for ''376''.

Par. (q)(1)(C). Pub. L. 102–300 added cl. (C).

1990—Par. (e). Pub. L. 101–502 substituted ''or (k)'' for ''or (j)''.

Par. (j). Pub. L. 101–508 inserted at end ''This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.''

1988—Par. (t). Pub. L. 100–293 added par. (t).

1986—Par. (s). Pub. L. 99–570 amended par. (s) generally. Prior to amendment, par. (s) read as follows: ''The failure to provide the notice required by section 350a(b) or 350a(c), the failure to make the reports required by section 350a(d)(1)(B), or the failure to meet the requirements prescribed under section 350a(d)(2).''

1980—Par. (e). Pub. L. 96–359, §5(b), inserted reference to section 350a of this title in two places.

Par. (j). Pub. L. 96–359, §5(c), inserted reference to section 350a of this title.

Par. (s). Pub. L. 96–359, §5(a), added par. (s).

1976—Par. (e). Pub. L. 94–295, §3(b)(2), inserted references to sections 360e(f) and 360i of this title.

Par. (j). Pub. L. 94–295, §3(b)(3), inserted references to sections 360, 360c, 360d, 360e, 360f, 360h, 360i, 360j, and 379 of this title.

Par. (*l*). Pub. L. 94–295, §3(b)(4), substituted ''drug or device'' for ''drug'' wherever appearing, and inserted references to sections 360e and 360j(g) of this title.

Par. (p). Pub. L. 94–295, §4(b)(1), substituted ''section 360(j) or 360(k) of this title,'' for ''section 360(j) of this title,''.

Par. (q). Pub. L. 94–295, §3(b)(1), added par. (q).

Par. (r). Pub. L. 94–295, §7(b), added par. (r).

[1] So in original. Probably should be ''(v)''.

1972—Par. (p). Pub. L. 92–387 added failure to provide information required by section 360(j) of this title, and failure to provide notice required by section 360(j)(2) of this title as prohibited acts.

1970—Par. (q). Pub. L. 91–513 struck out par. (q) which set out penalties for illegal manufacture, sale, disposition, possession and other traffic in stimulant and depressant drugs. See section 801 et seq. of this title.

1968—Par. (e). Pub. L. 90–399, § 103(1), inserted reference to section 360b(j), (*l*), and (m) of this title.

Par. (j). Pub. L. 90–399, § 103(2), inserted reference to section 360b of this title.

Par. (q). Pub. L. 90–639 divided cl. (3), which referred simply to possession in violation of section 360a(c) of this title, into subcls. (A) and (B) which refer, respectively, to possession in violation of section 360a(c)(1) of this title and possession in violation of section 360a(c)(2) of this title.

1965—Par. (i). Pub. L. 89–74, § 9(c), designated existing provisions as subpar. (1) and added subpars. (2) and (3).

Par. (q). Pub. L. 89–74, § 5, added par. (q).

1962—Par. (e). Pub. L. 87–781, §§ 103(c), 106(c), prohibited the failure to establish or maintain any record, or make any report, required under sections 355(i) or (j) and 507(d) or (g) of this title, or the refusal to permit access to, or verification or copying of, any such required record.

Par. (*l*). Pub. L. 87–781, § 104(e)(1), inserted ''approval of'' before ''an application'', and substituted ''in effect'' for ''effective''.

Par. (*o*). Pub. L. 87–781, § 114(a), added par. (*o*).

Par. (p). Pub. L. 87–781, § 304, added par. (p).

1960—Par. (i). Pub. L. 86–618, § 105(a), struck out references to sections 346(b), 354, and 364 of this title and inserted reference to section 376 of this title.

Par. (j). Pub. L. 86–618, § 104, inserted reference to section 376 of this title.

1958—Par. (j). Pub. L. 85–929, inserted reference to section 348 of this title.

1953—Par. (n). Act Aug. 7, 1953, added par. (n).

1950—Par. (m). Act Mar. 16, 1950, added par. (m).

1948—Par. (k). Act June 24, 1948, inserted ''(whether or not the first sale)'' so as to make it clear that this subsection is not limited to the case where the act occurs while the article is held for the first sale after interstate shipment, and extended coverage of subsection to acts which result in adulteration.

1947—Par. (j). Act Mar. 10, 1947, inserted reference to sections 356 and 357 of this title.

1945—Par. (i). Act July 6, 1945, inserted reference to section 357 of this title.

1941—Par. (i). Act Dec. 22, 1941, inserted reference to section 356 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–396 effective upon adoption of final regulations under section 2(c) of Pub. L. 103–396, set out as a Regulations note under section 360b of this title, see section 2(d) of Pub. L. 103–396, set out as a note under section 360b of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Section 4755(c)(2) of Pub. L. 101–508 provided that the amendment made by that section is effective as if included in subtitle D of title VI of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–239, title VI, §§ 6601, 6602, Dec. 19, 1989, 103 Stat. 2285, see 42 U.S.C. 300aa–1 note, 300aa–10 note.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100–293, set out as a note under section 353 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–387 effective on first day of sixth month beginning after Aug. 16, 1972, see section 5 of Pub. L. 92–387, set out as a note under section 360 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

Amendment by Pub. L. 90–639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90–639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective Feb. 1, 1966, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by sections 103(c) and 106(c) of Pub. L. 87–781 effective on first day of seventh calendar month following Oct. 1962, and amendment by section 104(e)(1) of Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

Section 114(b) of Pub. L. 87–781 provided that: ''This section [amending this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [October 1962].''

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF 1958 AMENDMENT

Amendment by Pub. L. 85–929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of that act, set out as an Effective Date note under section 347 of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 332, 333, 347b, 360i, 360j of this title; title 42 section 1396r–8.

## § 332. Injunction proceedings

### (a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown[1] to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

### (b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

(June 25, 1938, ch. 675, § 302, 52 Stat. 1043; Oct. 10, 1962, Pub. L. 87–781, title I, § 103(d), title II, § 201(c), 76 Stat. 784, 793; Aug. 13, 1993, Pub. L. 103–80, § 3(d), 107 Stat. 775.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–80, § 3(d)(1), struck out '', and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes', approved October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 381),'' after ''for cause shown''.

Subsec. (b). Pub. L. 103–80, § 3(d)(2), struck out at end ''Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387).''

1962—Subsec. (a). Pub. L. 87–781, § 103(d), struck out ''(e),'' after ''paragraphs''.

Pub. L. 87–781, § 201(c), struck out ''(f),'' after ''paragraphs''.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by section 103(c) of Pub. L. 87–781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

Section 203 of title II of Pub. L. 87–781 provided that: ''The amendments made by this title [amending this section and section 374 of this title and enacting provisions set out as notes under sections 321 and 374 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 360j of this title; title 42 section 1396r–8.

## § 333. Penalties

### (a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,[1] if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

### (b) Prescription drug marketing violations

(1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than $100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relat-

[1] So in original. Probably should be followed by a comma.

[1] So in original. Words ''of this section'' probably should not appear.

ing to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

**(c) Exceptions in certain cases of good faith, etc.**

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) nor 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

**(d) Exceptions involving misbranded food**

No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 331 of this title involving misbranded food if the violation exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising.

**(e) Prohibited distribution of human growth hormone**

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [21 U.S.C. 801 et seq.] for the purposes of forfeiture under section 413 of such Act [21 U.S.C. 853].

(4) As used in this subsection the term ''human growth hormone'' means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

**(f) Violations related to devices**

(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 360i(a) or 360j(f) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 360i(e) or 360i(f) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2)(A) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested, in accordance with paragraph (2)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(4) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(June 25, 1938, ch. 675, §303, 52 Stat. 1043; Oct. 26, 1951, ch. 578, §2, 65 Stat. 649; July 12, 1960, Pub. L. 86–618, title I, §105(b), 74 Stat. 403; July 15, 1965, Pub. L. 89–74, §§7, 9(d), 79 Stat. 233, 235; Oct. 24, 1968, Pub. L. 90–639, §3, 82 Stat. 1361; Oct. 27, 1970, Pub. L. 91–513, title II, §701(b), 84 Stat. 1281; Apr. 22, 1976, Pub. L. 94–278, title V, §502(a)(2)(B), 90 Stat. 411; Apr. 22, 1988, Pub. L. 100–293, §7(b), 102 Stat. 99; Nov. 18, 1988, Pub. L. 100–690, title II, §2403, 102 Stat. 4230; Nov. 28, 1990, Pub. L. 101–629, §17(a), 104 Stat. 4526; Nov. 29, 1990, Pub. L. 101–647, title XIX, §1904, 104 Stat. 4853; Aug. 26, 1992, Pub. L. 102–353, §3, 106 Stat. 941; Aug. 13, 1993, Pub. L. 103–80, §3(e), 107 Stat. 775; Sept. 13, 1994, Pub. L. 103–322, title XXXIII, §330015, 108 Stat. 2146.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (e)(3), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, which is classified principally to subchapter I (§801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

1994—Subsec. (e). Pub. L. 103–322 amended directory language of Pub. L. 101–647. See 1990 Amendment note below.

1993—Subsecs. (e) to (g). Pub. L. 103–80, which directed the amendment of this section by redesignating the second subsec. (e) and subsec. (f) as subsecs. (f) and (g), respectively, could not be executed because this section did not contain a second subsec. (e) subsequent to amendment of Pub. L. 101–647 by Pub. L. 103–322. See 1990 and 1994 amendment notes for subsec. (e) under this section.

1992—Subsec. (b)(1). Pub. L. 102–353, §3(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title because of an importation of a drug in violation of section 381(d)(1) of this title, because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, or the distribution of drugs in violation of section 353(e)(2)(A) of this title shall be imprisoned for not more than 10 years or fined not more than $250,000, or both."

Subsec. (b)(4)(A). Pub. L. 102–353, §3(b)(1), substituted "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (b)(4)(B)(i). Pub. L. 102–353, §3(b)(1), (2), substituted "before the institution of a criminal proceeding against" for "before the arrest of" and "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (b)(5). Pub. L. 102–353, §3(b)(3), substituted "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (c). Pub. L. 102–353, §3(b)(4), substituted "subsection (a)(1) of this section" for "subsection (a) of this section".

Subsec. (d). Pub. L. 102–353, §3(b)(4), (5), substituted "subsection (a)(1) of this section" for "subsection (a) of this section" and struck out ", and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed

with the intent to defraud or mislead'' after ''advertising''.

1990—Subsec. (e). Pub. L. 101–647, as amended by Pub. L. 103–322, amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows:

''(e)(1) Except as provided in paragraph (2), any person who distributes or possesses with the intent to distribute any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than three years or fined under title 18, or both.

''(2) Any person who distributes or possesses with the intent to distribute to an individual under 18 years of age, any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than six years or fined under title 18, or both.''

Subsec. (f). Pub. L. 101–629 added subsec. (f).

1988—Subsecs. (a), (b). Pub. L. 100–293 designated existing subsecs. (a) and (b) as pars. (1) and (2) of subsec. (a), substituted ''paragraph (1)'' for ''subsection (a)'' in par. (2), and added subsec. (b).

Subsec. (e). Pub. L. 100–690 added subsec. (e).

1976—Subsec. (d). Pub. L. 94–278 added subsec. (d).

1970—Subsec. (a). Pub. L. 91–513 struck out reference to subsec. (b) and transferred to subsec. (b) provisions covering second offenses and offenses committed with intent to defraud or mislead.

Subsec. (b). Pub. L. 91–513 inserted provisions covering second offenses and offenses committed with intent to defraud or mislead formerly set out in subsec. (a) and struck out provisions covering violations involving depressant and stimulant drugs. See section 801 et seq. of this title.

1968—Subsecs. (a), (b). Pub. L. 90–639 made a general revision in the penalties prescribed for offenses involving depressant or stimulant drugs, set a fine of not to exceed $10,000 or imprisonment of not more than 5 years for offenses involving the unlawful manufacturing of, sale, or disposal of, or possession with intent to sell, a depressant or stimulant drug or involving counterfeit depressant or stimulant drugs, stiffened the penalties for unlawful sales or other disposals by persons over 18 to persons under 21, and set new penalties for possession of a depressant or stimulant drug for purposes other than sale or other disposal.

1965—Subsec. (a). Pub. L. 89–74, § 7(a), inserted proviso limiting the penalties for depressant or stimulant drug violations to two years imprisonment or $5,000 fine or both for first offense and to two years imprisonment or $15,000 fine or both for subsequent offenses.

Subsec. (b). Pub. L. 89–74, § 7(b), inserted parenthetical exception provision.

Subsec. (c)(5). Pub. L. 89–74, § 9(d), added cl. (5).

1960—Subsec. (c)(3). Pub. L. 86–618 substituted ''a color additive'' for ''a coal-tar color'', ''the color additive'' for ''the coal-tar color'' and ''such color additive was'' for ''such color was''.

1951—Subsec. (c)(4). Act Oct. 26, 1951, added cl. (4).

EFFECTIVE DATE OF 1994 AMENDMENT

Section 330015 of Pub. L. 103–322 provided that the amendment made by that section is effective as of the date on which section 1904 of Pub. L. 101–647, which amended this section, took effect.

EFFECTIVE DATE OF 1990 AMENDMENT

Section 17(b) of Pub. L. 101–629 provided that:

''(b) EFFECTIVE DATE OF APPLICATION TO DEVICE USER FACILITIES.—

''(1) The Secretary of Health and Human Services shall conduct a study to determine whether there has been substantial compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)] by device user facilities (as defined in section 519(b)(5)(A) of such Act). The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act [Nov. 28, 1990].

''(2)(A) If upon the expiration of 48 months after the date of the enactment of this Act [Nov. 28, 1990] the Secretary has not made the report required by paragraph (1), section 303(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333(f)], as added by the amendment made by subsection (a), shall take effect with respect to device user facilities (as defined in section 519(b)(5)(A) of such Act). [Secretary of Health and Human Services had not made the report required by par. (1) on the expiration of 48 months after Nov. 28, 1990.]

''(B) If in the report under paragraph (1) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by a type of device user facility and if the Secretary does not make a determination under subparagraph (C) with respect to such type of facility, such section 303(f) shall not take effect with respect to such type of facility.

''(C) If the Secretary determines in the report under paragraph (1) that there is not substantial compliance with the requirements of such section 519(b) by a type of device user facility or if the Secretary makes such a determination after making the report under paragraph (1), such section 303(f) shall take effect with respect to such type of facility upon the effective date of the report.''

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100–293, set out as a note under section 353 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94–278, set out as a note under section 334 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90–639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective Feb. 1, 1966, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF 1951 AMENDMENT

Section 3 of act Oct. 26, 1951, provided that: ''The provisions of this Act [amending this section and section 353 of this title] shall take effect six months after the date of its enactment [Oct. 26, 1951].''

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in ac-

cord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

ENFORCEMENT

Pub. L. 99–660, title I, § 103, Nov. 14, 1986, 100 Stat. 3751, provided that: ''For the fines authorized to be imposed under section 303 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333], see section 3623 of title 18, United States Code, for the period ending October 31, 1986 [probably should be October 31, 1987], and sections 3559 and 3571 of such title for the period beginning November 1, 1986 [probably should be November 1, 1987].''

CROSS REFERENCES

Furnishing of guaranties, applicability to raw agricultural commodities, see section 346a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 346a, 360j, 859 of this title; title 15 section 1456.

### § 333a. Repealed. Pub. L. 101–647, title XIX, § 1905, Nov. 29, 1990, 104 Stat. 4853

Section, Pub. L. 100–690, title II, § 2401, Nov. 18, 1988, 102 Stat. 4230, related to forfeiture and illegal trafficking in steroids or human growth hormones.

### § 334. Seizure

#### (a) Grounds and jurisdiction

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and (D) Any adulterated or misbranded device.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

(i) is misbranded under section 343(a)(2) of this title because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i)(I) the food's advertising which resulted in the food being misbranded under section 343(a)(2) of this title was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

#### (b) Procedure; multiplicity of pending proceedings

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed

upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

**(c) Availability of samples of seized goods prior to trial**

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

**(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures**

(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter, under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 381(e) of this title can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6), section 351(a)(3), section 352(j), or section 361(a) or (d) of this title. Where such exportation is made to the original foreign supplier, then paragraphs (1) and (2) of section 381(e) of this title and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(e) of this title have been met. Any article condemned by reason of its being an article which may not, under section 344 or 355 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a) of this section.

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a) of this section, the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

**(e) Costs**

When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

**(f) Removal of case for trial**

In the case of removal for trial of any case as provided by subsection (a) or (b) of this section—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

**(g) Administrative restraint; detention orders**

(1) If during an inspection conducted under section 374 of this title of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of deten-

tion greater than twenty days is required to institute an action under subsection (a) of this section or section 332 of this title, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) of this section may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) released by the Secretary, or

(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

(B) A device subject to a detention order under paragraph (1) may be moved—

(i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.

(June 25, 1938, ch. 675, §304, 52 Stat. 1044; June 24, 1948, ch. 613, §2, 62 Stat. 582; Aug. 7, 1953, ch. 350, §3, 67 Stat. 477; Aug. 31, 1957, Pub. L. 85–250, 71 Stat. 567; July 15, 1965, Pub. L. 89–74, §6, 79 Stat. 232; Oct. 24, 1968, Pub. L. 90–639, §4(b), 82 Stat. 1362; Oct. 27, 1970, Pub. L. 91–513, title II, §701(c), (d), 84 Stat. 1281, 1282; Apr. 22, 1976, Pub. L. 94–278, title V, §502(a)(2)(C), 90 Stat. 411; May 28, 1976, Pub. L. 94–295, §§3(c), 7(a), 90 Stat. 576, 582; June 16, 1992, Pub. L. 102–300, §6(c), 106 Stat. 240; Aug. 13, 1993, Pub. L. 103–80, §3(f), 107 Stat. 775.)

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–80, §3(f)(1), substituted ''found. No libel'' for ''found: *Provided, however*, That no libel''.

Subsec. (d)(1). Pub. L. 103–80, §3(f)(2), substituted ''sold. After entry'' for ''sold: *Provided*, That after entry'', ''met. The provisions of this sentence'' for ''met: *Provided, however*, That the provisions of this sentence'', ''title. Where such exportation'' for ''title: *And provided further*, That where such exportation'', and ''the preceding sentence shall not be applicable'' for ''the foregoing proviso shall not be applicable''.

1992—Subsec. (d)(1). Pub. L. 102–300 substituted ''381(e)'' for ''381(d)'' in three places and ''paragraphs'' for ''clauses'' before ''(1) and (2) of section 381(e)''.

1976—Subsec. (a)(1). Pub. L. 94–295, §3(c)(1), struck out ''device,'' after ''Any article of food, drug,''.

Subsec. (a)(2). Pub. L. 94–295, §3(c)(2), (3), added cl. (D) covering adulterated or misbranded devices.

Subsec. (a)(3). Pub. L. 94–278 added par. (3).

Subsec. (g). Pub. L. 94–295, §7(a), added subsec. (g).

1970—Subsec. (a)(2). Pub. L. 91–513, §701(c), struck out cls. (A) and (D) which dealt with depressant or stimulant drugs, struck out reference to depressant or stimulant drugs in cl. (C), and redesignated cls. (B), (C), and (E) as cls. (A), (B), and (C), respectively.

Subsec. (d)(3)(iii). Pub. L. 91–513, §701(d), struck out reference to depressant or stimulant drugs.

1968—Subsec. (a). Pub. L. 90–639 inserted references to the United States courts of Territories.

1965—Subsec. (a). Pub. L. 89–74, §6(a), designated existing provisions as par. (1), redesignated cls. (1) and (2) of proviso as (A) and (B), and added par. (2).

Subsec. (b). Pub. L. 89–74, §6(b)(1), inserted ''equipment, or other thing proceeded against'' after ''article'' in first sentence.

Subsec. (d). Pub. L. 89–74, §6(b)(2), designated existing provisions as par. (1), redesignated cls. (1) and (2) of the second sentence thereof as (A) and (B), and added pars. (2) and (3).

1957—Subsec. (d). Pub. L. 85–250 permitted, under certain circumstances, reexportation of articles condemned at places other than original port of entry.

1953—Subsec. (c). Act Aug. 7, 1953, provided that a true copy of the analysis in any case shall be furnished the owner.

1948—Subsec. (a). Act June 24, 1948, inserted ''or while held for sale (whether or not the first sale) after shipment in interstate commerce'' to make this subsection coextensive with section 331(k) of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Section 502(c) of Pub. L. 94–278 provided that: ''The amendments made by subsection (a) [amending this section and sections 321, 333, and 343 of this title] shall take effect 180 days after the date of the enactment of this Act [Apr. 22, 1976].''

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90–639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective Feb. 1, 1966, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

FEDERAL RULES OF CIVIL PROCEDURE

Admiralty and maritime rules of practice (which included libel procedures) were superseded, and civil and

admiralty procedures in United States district courts were unified, effective July 1, 1966, see rule 1 and Supplemental Rules for Certain Admiralty and Maritime Claims, Title 28, Appendix, Judiciary and Judicial Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360j, 372 of this title; title 42 section 1396r–8.

### § 335. Hearing before report of criminal violation

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

(June 25, 1938, ch. 675, § 305, 52 Stat. 1045.)

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

### § 335a. Debarment, temporary denial of approval, and suspension

**(a) Mandatory debarment**

**(1) Corporations, partnerships, and associations**

If the Secretary finds that a person other than an individual has been convicted, after May 13, 1992, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

**(2) Individuals**

If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this chapter,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

**(b) Permissive debarment**

**(1) In general**

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2), debar—

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application, or

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application.

**(2) Persons subject to permissive debarment**

The following persons are subject to debarment under paragraph (1):

**(A) Corporations, partnerships, and associations**

Any person other than an individual that the Secretary finds has been convicted—

(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before May 13, 1992), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1) of this section,

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

**(B) Individuals**

(i) Any individual whom the Secretary finds has been convicted of—

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this chapter, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2) of this section,

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of—

(I) a felony which is not described in subsection (a)(2) of this section or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) of this section or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to

find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iv) Any high managerial agent whom the Secretary finds—

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2) of this section, or clause (i), of such other individual,

(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge,

(III) knew that the actions described in subclause (I) were violative of law, and

(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions,

if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

**(3) Stay of certain orders**

An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

**(c) Debarment period and considerations**

**(1) Effect of debarment**

The Secretary—

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) of this section during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B) of this section, debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 335b(a) of this title, assess a civil penalty in accordance with section 335b of this title.

**(2) Debarment periods**

**(A) In general**

The Secretary shall debar a person under subsection (a) or (b) of this section for the following periods:

(i) The period of debarment of a person (other than an individual) under subsection (a)(1) of this section shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) of this section occurs within 10 years after such person has been debarred under subsection (a)(1) of this section, the period of debarment shall be permanent.

(ii) The debarment of an individual under subsection (a)(2) of this section shall be permanent.

(iii) The period of debarment of any person under subsection (b)(2) of this section shall not be more than 5 years.

The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

**(B) Notification**

Upon a conviction for an offense described in subsection (a) or (b) of this section or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Secretary that the person acquiesces to debarment and such person's debarment shall commence upon such notification.

**(3) Considerations**

In determining the appropriateness and the period of a debarment of a person under subsection (b) of this section and any period of debarment beyond the minimum specified in subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable—

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this chapter or under other Acts involving matters within

the jurisdiction of the Food and Drug Administration.

**(d) Termination of debarment**

**(1) Application**

Any person that is debarred under subsection (a) of this section (other than a person permanently debarred) or any person that is debarred under subsection (b) of this section may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

**(2) Deadline**

The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

**(3) Action by the Secretary**

**(A) Corporations**

**(i) Conviction reversal**

If the conviction which served as the basis for the debarment of a person under subsection (a)(1) or (b)(2)(A) of this section is reversed, the Secretary shall withdraw the order of debarment.

**(ii) Application**

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that—

(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future, and

(II) sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

In the case of persons debarred under subsection (a)(1) of this section, such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

**(B) Individuals**

**(i) Conviction reversal**

If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) of this section or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) of this section is reversed, the Secretary shall withdraw the order of debarment.

**(ii) Application**

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) of this section if such termination serves the interests of justice and adequately protects the integrity of the drug approval process.

**(4) Special termination**

**(A) Application**

Any person that is debarred under subsection (a)(1) of this section (other than a person permanently debarred under subsection (c)(2)(A)(i) of this section) or any individual who is debarred under subsection (a)(2) of this section may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

**(B) Corporations**

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment,

(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offense have been removed from employment involving the development or approval of any drug subject to sections 355 or 357 of this title,

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

**(C) Individuals**

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such individual has provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) of this section or which relate to any matter under the jurisdiction of the Food and Drug Administration.

**(D) Secretarial action**

The action referred to in subparagraphs (B) and (C) is—

(i) in the case of a person other than an individual—

(I) terminating the debarment immediately, or

(II) limiting the period of debarment to less than one year, and

(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year,

whichever best serves the interest of justice and protects the integrity of the drug approval process.

**(e) Publication and list of debarred persons**

The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b) of this section, the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

**(f) Temporary denial of approval**

**(1) In general**

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve any abbreviated drug application submitted by any person—

(A) if such person is under an active Federal criminal investigation in connection with an action described in subparagraph (B),

(B) if the Secretary finds that such person—

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such actions, or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department of Health and Human Services, or has conspired to commit, or aided or abetted, such actions, and

(C) if a significant question has been raised regarding—

(i) the integrity of the approval process with respect to such abbreviated drug application, or

(ii) the reliability of data in or concerning such person's abbreviated drug application.

Such an order may be modified or terminated at any time.

**(2) Applicable period**

**(A) In general**

Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial—

(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

(ii) if the Secretary determines that such finding was in error.

**(B) Extension**

If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

**(3) Informal hearing**

Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

**(g) Suspension authority**

**(1) In general**

If—

(A) the Secretary finds—

(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) of this section in connection with 2 or more drugs under abbreviated drug applications, or

(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2-year period, and—

(I) such violations may undermine the safety and efficacy of such drugs, and

(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A),

the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

**(2) Public health waiver**

The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

**(h) Termination of suspension**

The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) of this section if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this chapter, and

(B) changes in ownership, management, or operations—

(i) fully remedy the patterns or practices with respect to which the order was issued, and

(ii) provide reasonable assurances that such actions will not occur in the future, or

(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

**(i) Procedure**

The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

**(j) Judicial review**

**(1) In general**

Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

**(2) Exception**

Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) of this section may obtain a review of such decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

**(k) Certification**

Any application for approval of a drug product shall include—

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) of this section, in connection with such application, and

(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) of this section which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

**(*l*) Applicability**

**(1) Conviction**

For purposes of this section, a person is considered to have been convicted of a criminal offense—

(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld.

**(2) Effective dates**

Subsection (a) of this section, subparagraph (A) of subsection (b)(2) of this section, and

clauses (i) and (ii) of subsection (b)(2)(B) of this section shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b) of this section. Clauses (iii) and (iv) of subsection (b)(2)(B) of this section and subsections (f) and (g) of this section shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g) of this section. Clause (iv) of subsection (b)(2)(B) of this section shall not apply to an action which occurred before June 1, 1992. Subsection (k) of this section shall not apply to applications submitted to the Secretary before June 1, 1992.

(June 25, 1938, ch. 675, § 306, as added May 13, 1992, Pub. L. 102–282, § 2, 106 Stat. 150.)

PRIOR PROVISIONS

A prior section 306 of act June 25, 1938, was renumbered section 309 and is classified to section 336 of this title.

CONSTRUCTION

Section 7 of Pub. L. 102–282 provided that: ''No amendment made by this Act [enacting this section and sections 335b and 335c of this title and amending sections 321, 336, 337, and 355 of this title] shall preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by this Act.''

CONGRESSIONAL FINDINGS

Section 1(c) of Pub. L. 102–282 provided that: ''The Congress finds that—

''(1) there is substantial evidence that significant corruption occurred in the Food and Drug Administration's process of approving drugs under abbreviated drug applications,

''(2) there is a need to establish procedures designed to restore and to ensure the integrity of the abbreviated drug application approval process and to protect the public health, and

''(3) there is a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 335b of this title.

## § 335b. Civil penalties

### (a) In general

Any person that the Secretary finds—

(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

(6) is a person that has an approved or pending drug product application and has knowingly—

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of,

a person who was debarred under section 335a of this title, or

(7) is an individual debarred under section 335a of this title and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application,

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

### (b) Procedure

#### (1) In general

##### (A) Action by the Secretary

A civil penalty under subsection (a) of this section shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

##### (B) Action by the Attorney General

In lieu of a proceeding under subparagraph (A), the Attorney General may, upon request of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a) of this section. Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this chapter.

#### (2) Amount

In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act

subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

**(3) Limitation on actions**

No action may be initiated under this section—

(A) with respect to any act described in subsection (a) of this section that occurred before May 13, 1992, or

(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

**(c) Judicial review**

Any person that is the subject of an adverse decision under subsection (b)(1)(A) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

**(d) Recovery of penalties**

The Attorney General may recover any civil penalty (plus interest at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) of this section in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

**(e) Informants**

The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a) of this section) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed—

(1) $250,000, or

(2) one-half of the penalty so imposed and collected,

whichever is less. The decision of the Secretary on such award shall not be reviewable.

(June 25, 1938, ch. 675, § 307, as added May 13, 1992, Pub. L. 102–282, § 3, 106 Stat. 159; amended Aug. 13, 1993, Pub. L. 103–80, § 3(g), 107 Stat. 776.)

PRIOR PROVISIONS

A prior section 307 of act June 25, 1938, was renumbered section 310 and is classified to section 337 of this title.

AMENDMENTS

1993—Subsec. (b)(3)(A). Pub. L. 103–80 made technical amendment to reference to May 13, 1992, to reflect correction of corresponding provision of original act.

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102–282, see section 7 of Pub. L. 102–282, set out as a note under section 335a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 335a of this title.

## § 335c. Authority to withdraw approval of abbreviated drug applications

**(a) In general**

The Secretary—

(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement, and

(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

**(b) Procedure**

The Secretary may not take any action under subsection (a) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

**(c) Applicability**

Subsection (a) of this section shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

**(d) Judicial review**

Any person that is the subject of an adverse decision under subsection (a) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(June 25, 1938, ch. 675, § 308, as added May 13, 1992, Pub. L. 102–282, § 4, 106 Stat. 160.)

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102–282, see section 7 of Pub. L. 102–282, set out as a note under section 335a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title.

### § 336. Report of minor violations

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(June 25, 1938, ch. 675, § 309, formerly § 306, 52 Stat. 1045; renumbered § 309, May 13, 1992, Pub. L. 102–282, § 2, 106 Stat. 150.)

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

FEDERAL RULES OF CIVIL PROCEDURE

Admiralty and maritime rules of practice (which included libel procedures) were superseded, and civil and admiralty procedures in United States district courts were unified, effective July 1, 1966, see rule 1 and Supplemental Rules for Certain Admiralty and Maritime Claims, Title 28, Appendix, Judiciary and Judicial Procedure.

### § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

(June 25, 1938, ch. 675, § 310, formerly § 307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, § 37, 68 Stat. 1239; Nov. 8, 1990, Pub. L. 101–535, § 4, 104 Stat. 2362; renumbered § 310, May 13, 1992, Pub. L. 102–282, § 2, 106 Stat. 150.)

AMENDMENTS

1990—Pub. L. 101–535 substituted ''(a) Except as provided in subsection (b) of this section, all'' for ''All'' and ''any proceeding under this section'' for ''any such proceeding'' and added subsec. (b).

1954—Act Sept. 3, 1954, struck out reference to section 654 of title 28.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–535 effective 24 months after Nov. 8, 1990, except that such amendment effective Dec. 31, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 10(a)(1)(C) of Pub. L. 101–535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101–535

Amendments by Pub. L. 101–535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101–535, set out as a note under section 343 of this title.

## SUBCHAPTER IV—FOOD

### § 341. Definitions and standards for food

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

(June 25, 1938, ch. 675, § 401, 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919; Aug. 13, 1993, Pub. L. 103–80, § 3(h), 107 Stat. 776.)

AMENDMENTS

1993—Pub. L. 103–80 substituted ''or reasonable standards of fill of container. No definition'' for ''and/or reasonable standards of fill of container: *Provided*, That no definition''.

1956—Act Aug. 1, 1956, designated provisions constituting subsec. (a) as entire section and repealed subsec. (b) which provided the procedure for establishment of regulations and is covered by section 371(e) of this title.

1954—Act Apr. 15, 1954, designated existing provisions as subsec. (a) and added subsec. (b).

SAVINGS PROVISION

Section 3 of act Aug. 1, 1956, provided that: ''In any case in which, prior to the enactment of this Act [Aug. 1, 1956], a public hearing has been begun in accordance with section 401 of the Federal Food, Drug, and Cosmetic Act [341 of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by such section, or has been begun in accordance with section 701(e) of such Act [section 371(e) of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by section 403(j), 404(a), 406(a) or (b), 501(b), 502(d), 502(h), 504 or 604 of such Act [section 343(j), 344(a), 346(a) or (b), 351(b), 352(d), 352(h), 354, or 364 of this title], the provisions of such section 401 or 701(e), as the case may be, as in force immediately prior to the date of the enactment of this Act [Aug. 1, 1956], shall be applicable as though this Act [amending this section and section 371(e) of this title] had not been enacted.''

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 337, 343, 343–1, 350, 371 of this title.

## § 342. Adulterated food

A food shall be deemed to be adulterated—

### (a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[1] (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or if it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; (3) If[2] it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

### (b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

### (c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

### (d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is per-

[1] So in original. The period probably should be ''; or''.

[2] So in original. Probably should be ''or (3) if''.

mitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

**(e) Oleomargarine containing filthy, putrid, etc., matter**

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

**(f) Dietary supplement or ingredient: safety**

(1) If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph[3] (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

**(g) Dietary supplement: manufacturing practices**

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(June 25, 1938, ch. 675, § 402, 52 Stat. 1046; Mar. 16, 1950, ch. 61, § 3(d), 64 Stat. 21; July 22, 1954, ch. 559, § 2, 68 Stat. 511; July 9, 1956, ch. 530, 70 Stat. 512; Sept. 6, 1958, Pub. L. 85–929, § 3(a), (b), 72 Stat. 1784; Mar. 17, 1959, Pub. L. 86–2, 73 Stat. 3; July 12, 1960, Pub. L. 86–618, title I, §§ 102(a)(1), (2), 105(c), 74 Stat. 397, 398, 404; June 29, 1966, Pub. L. 89–477, 80 Stat. 231; July 13, 1968, Pub. L. 90–399, § 104, 82 Stat. 352; Feb. 27, 1986, Pub. L. 99–252, § 10, 100 Stat. 35; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(4), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103–80, § 3(i), 107 Stat. 776; Oct. 25, 1994, Pub. L. 103–417, §§ 4, 9, 108 Stat. 4328, 4332.)

AMENDMENTS

1994—Par. (f). Pub. L. 103–417, § 4, added par. (f).

Par. (g). Pub. L. 103–417, § 9, added par. (g).

1993—Par. (a). Pub. L. 103–80, § 3(i)(1), substituted a period for "; or" at end of subpar. (1) and "If it" for "if it" at beginning of par. (3). That part of Pub. L. 103–80, § 3(i)(1), which directed the substitution of a period for "; or" at end of subpar. (2) could not be executed because "; or" did not appear.

Par. (d)(1). Pub. L. 103–80, § 3(i)(2), substituted ", except that this subparagraph" for ": *Provided*, That this clause".

Par. (d)(3). Pub. L. 103–80, § 3(i)(3), substituted ", except that this subparagraph shall not apply" for ": *Provided*, That this clause shall not apply" and ", except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph" for ": *And provided further*, That the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this clause".

1992—Par. (c). Pub. L. 102–571 substituted "379e(a)" for "376(a)".

1986—Par. (d)(2). Pub. L. 99–252 inserted provision that this clause not apply to confectionery introduced or delivered for introduction into or received or held for sale in, interstate commerce if the sale is permitted under the laws of the State in which the confectionery is intended to be offered for sale.

1968—Par. (a)(2). Pub. L. 90–399 added cls. (A)(iv) and (D).

1966—Par. (d). Pub. L. 89–477 permitted the imbedding of nonnutritive objects in confectionery foods if in the judgment of the Secretary of Health, Education, and Welfare, as provided by regulation, the imbedding of the object is of practical functional value to the confectionery product and would not render it injurious or hazardous to health, raised to one-half of 1 per centum by volume the upper limit for the allowable use of alco-

[3] So in original. Probably should be "subparagraph".

hol derived solely from the use of flavoring extracts, allowed the use of safe nonnutritive substances in and on confectionery foods by reason of their use for some practical and functional purpose in the manufacture, packaging, or storage of the confectionery foods if the use of the substances does not promote deception of the consumer or otherwise result in adulteration or misbranding, authorized the Secretary to issue regulations on the use of particular nonnutritive substances, and removed reference to nonnutritive masticatory substances added to chewing gum and harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, authorized coloring, and pectin.

1960—Par. (a). Pub. L. 86–618, §102(a)(1), substituted ''other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive'' for ''(except a pesticide chemical in or on a raw agricultural commodity and except a food additive)'' in cl. (2)(A).

Par. (c). Pub. L. 86–618, §102(a)(2), amended par. (c) generally, substituting provisions deeming a food adulterated if it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376 of this title for provisions which related to food that bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 346 of this title, and struck out provisos which related to the use of color on oranges.

Par. (d). Pub. L. 86–618, §105(c), substituted ''authorized coloring'' for ''harmless coloring''.

1959—Par. (c). Pub. L. 86–2 extended from Mar. 1, 1959, to May 1, 1959, the period during which subsection is inapplicable to oranges which have been colored with F.D. & C. Red 32, and inserted proviso requiring Secretary to establish regulations prescribing the conditions under which Citrus Red No. 2 may be safely used in coloring certain mature oranges, and providing for separately listing and for certification of batches of such color.

1958—Par. (a). Pub. L. 85–929, among other changes, inserted cl. (2)(C) relating to food additive unsafe within the meaning of section 348 of this title, and to pesticide chemical, and added cl. (7) relating to radiated food.

1956—Par. (c). Act July 9, 1956, inserted second proviso relating to coloring of oranges.

1954—Par. (a)(2). Act July 22, 1954, provided in the case of any raw agricultural commodity bearing or containing a pesticide chemical, that such commodity shall be deemed to be adulterated if such pesticide chemical is unsafe within the meaning of section 346a of this title.

1950—Par. (e). Act Mar. 16, 1950, added par. (e).

### Effective Date of 1968 Amendment

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

### Effective Date of 1960 Amendment

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

### Effective Date of Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959

Effective date of par. (a)(2) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86–139, Aug. 7, 1959, 73 Stat. 288.

### Effective Date of 1958 Amendment

Section 6 of Pub. L. 85–929, as amended by Pub. L. 87–19, §2, Apr. 7, 1961, 75 Stat. 42; Pub. L. 88–625, §2, Oct. 3, 1964, 78 Stat. 1002, provided that:

''(a) Except as provided in subsections (b) and (c) of this section, this Act [amending this section, sections 321, 331, 346, and 348 of this title, and section 210 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 321 and 451 of this title] shall take effect on the date of its enactment [Sept. 6, 1958].

''(b) Except as provided in subsection (c) of this section, section 3 of this Act [amending this section and section 346 of this title] shall take effect on the one hundred and eightieth day after the date of enactment of this Act [Sept. 6, 1958].

''(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act [amending this section and section 346 of this title] shall take effect—

''(1) Either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare [now Health and Human Services] may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

''(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act [section 348 of this title] becomes effective,

whichever date first occurs. Whenever the Secretary has, pursuant to clause (1)(B) of this subsection, extended the effective date of section 3 of this Act [amending this section] to March 5, 1961, or has on that date a request for such extension pending before him, with respect to any such particular use of a food additive, he may, notwithstanding the parenthetical time limitation in that clause, further extend such effective date, not beyond June 30, 1964, under the authority of that clause (but subject to clause (2)) with respect to such use of the additive (or a more limited specified use or uses thereof) if, in addition to making the findings required by clause (1)(B), he finds (i) that bona fide action to determine the applicability of such section 409 [section 348 of this title] to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (ii) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 409 [section 348 of this title]: *Provided*, That if the Secretary has, pursuant to this sentence, granted an extension to June 30, 1964, he may, upon making the findings required by clause (1)(B) of this subsection and clauses (i) and (ii) of this sentence, further extend such effective date, but not beyond December 31, 1965. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension.''

### Effective Date of 1954 Amendment

Section 5 of act July 22, 1954, provided that: ''This Act [amending this section and section 321 of this title and enacting sections 346a and 346b of this title] shall take effect upon the date of its enactment [July 22, 1954], except that with respect to pesticide chemicals for which tolerances or exemptions have not been es-

tablished under section 408 of the Federal Food, Drug, and Cosmetic Act [section 346a of this title], the amendment to section 402(a) of such Act [par. (a) of this section] made by section 2 of this Act shall not be effective—

''(1) for the period of one year following the date of the enactment of this Act [July 22, 1954]; or

''(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act [July 22, 1954] as the Secretary of Health, Education, and Welfare [now Health and Human Services] may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period.''

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as an Effective Date note under section 347 of this title.

EFFECTIVE DATE; POSTPONEMENT

Par. (c) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

SHORT TITLE

Pub. L. 88–625, § 1, Oct. 3, 1964, 78 Stat. 1002, provided: ''That this Act [amending provisions set out as a note under this section and section 135 of Title 7, Agriculture] may be cited as the 'Food Additives Transitional Provisions Amendment of 1964'.''

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

CROSS REFERENCES

Appropriations for establishing tolerances for pesticide chemicals, see section 346b of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 334, 346, 346a, 346b, 347b, 348, 350a, 350b, 360b, 379e of this title.

## § 343. Misbranded food

A food shall be deemed to be misbranded—

**(a) False or misleading label**

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

**(b) Offer for sale under another name**

If it is offered for sale under the name of another food.

**(c) Imitation of another food**

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and, immediately thereafter, the name of the food imitated.

**(d) Misleading container**

If its container is so made, formed, or filled as to be misleading.

**(e) Package form**

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

**(f) Prominence of information on label**

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

**(g) Representation as to definition and standard of identity**

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

**(h) Representation as to standards of quality and fill of container**

If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 341 of this title, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

**(i) Label where no representation as to definition and standard of identity**

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title[1] unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results

[1] So in original. Probably should be followed by a comma.

in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

**(j) Representation for special dietary use**

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

**(k) Artificial flavoring, artificial coloring, or chemical preservatives**

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

**(*l*) Pesticide chemicals on raw agricultural commodities**

If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

**(m) Color additives**

If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title.

**(n) Packaging or labeling of drugs in violation of regulations**

If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

**(*o*) Saccharin for immediate consumption**

(1) If it contains saccharin, unless, except as provided in subparagraph (2), its label and labeling bear the following statement: ''USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS''. Such statement shall be located in a conspicuous place on such label and labeling as proximate as possible to the name of such food and shall appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.

(2) The Secretary may by regulation review and revise or remove the requirement of subparagraph (1) if the Secretary determines such action is necessary to reflect the current state of knowledge concerning saccharin.

**(p) Saccharin not for immediate consumption**

(1) If it contains saccharin and is offered for sale, but not for immediate consumption, at a retail establishment, unless such retail establishment displays prominently, where such food is held for sale, notice (provided by the manufacturer of such food pursuant to subparagraph (2) for consumers respecting the information required by paragraph (*o*) to be on food labels and labeling.

(2) Each manufacturer of food which contains saccharin and which is offered for sale by retail establishments but not for immediate consumption shall, in accordance with regulations promulgated by the Secretary pursuant to subparagraph (4), take such action as may be necessary to provide such retail establishments with the notice required by subparagraph (1).

(3) The Secretary may by regulation review and revise or remove the requirement of subparagraph (1) if he determines such action is necessary to reflect the current state of knowledge concerning saccharin.

(4) The Secretary shall by regulation prescribe the form, text, and manner of display of the notice required by subparagraph (1) and such other matters as may be required for the implementation of the requirements of that subparagraph and subparagraph (2). Regulations of the Secretary under this subparagraph shall be promulgated after an oral hearing but without regard to the National Environmental Policy Act of 1969 [42 U.S.C. 4321 et seq.] and chapter 5 of title 5. In any action brought for judicial review of any such regulation, the reviewing court may not postpone the effective date of such regulation.

**(q) Nutrition information**

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after November 8, 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after November 8, 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(C)(i) Upon the expiration of 30 months after November 8, 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this subparagraph, the term ''fish'' includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

(iii) which is an infant formula subject to section 350a of this title,

(iv) which is a medical food as defined in section 360ee(b) of this title, or

(v) which is described in section 345(2) of this title.

(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E)(i) During the 12-month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if—

(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),

(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full-time equivalent employees,

(III) such person provided the notice described in subclause (iii), and

(IV) in the case of a food product which was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12-month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

(ii) During the 12-month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r), if such person provided the notice described in subclause (iii), and if—

(I) during the 12-month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 600,000 units of such product were sold in the United States,

(II) during the 12-month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or

(III) during the 12-month period preceding May 8, 1996, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which the exemption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall—

(I) state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,

(II) state the approximate number of units the person claiming the exemption sold in the United States,

(III) if the exemption is claimed for a food product which was sold in the 12-month period preceding the period for which the exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding period, and, if the exemption is claimed for a food

product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and

(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of such information.

If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.

(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after the date the number of full-time equivalent employees or food products sold exceeded the applicable number.

(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.

(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v)—

(I) the term ''unit'' means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,

(II) the term ''food product'' means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods, and

(III) the term ''person'' in the case of a corporation includes all domestic and foreign affiliates of the corporation.

(F) A dietary supplement product (including a food to which section 350 of this title applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that—

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(G) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

**(r) Nutrition levels and health-related claims**

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless—

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or

in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: ''See _____ for nutrition information.''. In the statement—

(i) the blank shall identify the panel on which the information described in the statement may be found, and

(ii) if the Secretary determines that the food contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the statement shall also identify such nutrient.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term ''diet'' and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term ''diet'' was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in subclause (i) shall describe—

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph

(2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary denies the petition, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 341 of this title shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: ''This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.''.

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

**(s) Dietary supplements**

If—

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list—

(i) the name of each ingredient of the supplement that is described in section 321(ff) of this title; and

(ii)(I) the quantity of each such ingredient; or

(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term ''dietary supplement'', which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section 321(ff)(1)(C) of this title, and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

(D) the supplement—

(i) is covered by the specifications of an official compendium;

(ii) is represented as conforming to the specifications of an official compendium; and

(iii) fails to so conform; or

(E) the supplement—

(i) is not covered by the specifications of an official compendium; and

(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

(II) fails to meet the quality (including tablet or capsule disintegration), purity, or

compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

(June 25, 1938, ch. 675, § 403, 52 Stat. 1047; June 29, 1960, Pub. L. 86–537, § 1, 74 Stat. 251; July 12, 1960, Pub. L. 86–618, title I, § 102(a)(3), 74 Stat. 398; Dec. 30, 1970, Pub. L. 91–601, § 6(c), formerly § 7(c), 84 Stat. 1673, renumbered Aug. 13, 1981, Pub. L. 97–35, title XII, § 1205(c), 95 Stat. 716; Apr. 22, 1976, Pub. L. 94–278, title V, § 502(a)(1), 90 Stat. 411; Nov. 23, 1977, Pub. L. 95–203, § 4(a)(1), (b)(1), 91 Stat. 1452, 1453; Nov. 8, 1990, Pub. L. 101–535, §§ 2(a), 3(a), 7, 104 Stat. 2353, 2357, 2364; Aug. 17, 1991, Pub. L. 102–108, § 2(a), (c), 105 Stat. 549; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(5), (6), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103–80, §§ 2(b), 3(j), 107 Stat. 773, 776; Oct. 25, 1994, Pub. L. 103–417, §§ 6, 7(a)–(c), 10(c), 108 Stat. 4329, 4330, 4332.)

### References in Text

The National Environmental Policy Act of 1969, referred to in par. (p)(4), is Pub. L. 91–190, Jan. 1, 1970, 83 Stat. 852, as amended, which is classified generally to chapter 55 (§ 4321 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 4321 of Title 42 and Tables.

### Amendments

1994—Par. (q)(5)(F). Pub. L. 103–417, § 7(b), amended cl. (F) generally. Prior to amendment, cl. (F) read as follows: ''If a food to which section 350 of this title applies (as defined in section 350(c) of this title) contains one or more of the nutrients required by subparagraph (1) or (2) to be in the label or labeling of the food, the label or labeling of such food shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for such food and which is specified in regulations of the Secretary.''

Par. (r)(2)(F). Pub. L. 103–417, § 7(c), added cl. (F).

Par. (r)(6). Pub. L. 103–417, § 6, added subpar. (6).

Par. (s). Pub. L. 103–417, § 10(c), inserted at end: ''A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.''

Pub. L. 103–417, § 7(a), added par. (s).

1993—Par. (e). Pub. L. 103–80, § 3(j)(1), substituted ''count, except that'' for ''count: *Provided*, That''.

Par. (i). Pub. L. 103–80, § 3(j)(2), substituted ''unless sold as spices, flavorings, or such colors'' for '', other than those sold as such'' and ''naming each. To the extent'' for ''naming each: *Provided*, That, to the extent''.

Par. (k). Pub. L. 103–80, § 3(j)(3), substituted '', except that'' for '': *Provided*, That''.

Par. (*l*). Pub. L. 103–80, § 3(j)(4), substituted ''chemical, except that'' for ''chemical: *Provided, however*, That''.

Par. (q)(5)(E) to (G). Pub. L. 103–80, § 2(b), added cl. (E) and redesignated former cls. (E) and (F) as (F) and (G), respectively.

Par. (r)(1)(B). Pub. L. 103–80, § 3(j)(5), substituted ''(5)(D)'' for ''5(D)''.

Par. (r)(4)(B). Pub. L. 103–80, § 3(j)(6), substituted ''paragraph'' for ''subsection''.

1992—Par. (i). Pub. L. 102–571, § 107(5), substituted ''379e(c)'' for ''376(c)''.

Par. (m). Pub. L. 102–571, § 107(6), substituted ''379e'' for ''376''.

1991—Par. (i). Pub. L. 102–108, § 2(c), amended directory language of Pub. L. 101–535, § 7(1), (3). See 1990 Amendment note below.

Par. (q)(4)(A). Pub. L. 102–108, § 2(a), substituted ''(D)'' for ''(C)''.

1990—Par. (i). Pub. L. 101–535, § 7, as amended by Pub. L. 102–108, § 2(c), substituted ''Unless'' for ''If it is not subject to the provisions of paragraph (g) unless'', inserted ''and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food'', and substituted ''colors not required to be certified under section 376(c) of this title'' for ''colorings'' the first time appearing.

Par. (q). Pub. L. 101–535, § 2(a), added par. (q).

Par. (r). Pub. L. 101–535, § 3(a), added par. (r).

1977—Par. (*o*). Pub. L. 95–203, § 4(a)(1), added par. (*o*).

Par. (p). Pub. L. 95–203, § 4(b)(1), added par. (p).

1976—Par. (a). Pub. L. 94–278 inserted ''(1)'' after ''If'' and inserted '', or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title'' after ''any particular''.

1970—Par. (n). Pub. L. 91–601 added par. (n).

1960—Par. (k). Pub. L. 86–537, § 1(1), exempted pesticide chemicals when used in or on a raw agricultural commodity which is the produce of the soil.

Par. (*l*). Pub. L. 86–537, § 1(2), added par. (*l*).

Par. (m). Pub. L. 86–618 added par. (m).

### Effective Date of 1994 Amendment

Section 7(e) of Pub. L. 103–417 provided that: ''Dietary supplements—

''(1) may be labeled after the date of the enactment of this Act [Oct. 25, 1994] in accordance with the amendments made by this section [amending this section and section 350 of this title], and

''(2) shall be labeled after December 31, 1996, in accordance with such amendments.''

### Effective Date of 1990 Amendment

Section 10(a) of Pub. L. 101–535, as amended by Pub. L. 102–571, title II, § 202(a)(3), Oct. 29, 1992, 106 Stat. 4501, provided that:

''(1) Except as provided in paragraph (2)—

''(A) the amendments made by section 2 [amending this section] shall take effect 6 months after—

''(i) the date of the promulgation of all final regulations required to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)], or

''(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations [Nov. 8, 1992, see 57 F.R. 56347],

except that section 403(q)(4) of such Act shall take effect as prescribed by such section,

''(B) the amendments made by section 3 [amending this section] shall take effect 6 months after—

''(i) the date of the promulgation of final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, or

''(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations [Nov. 8, 1992, see 57 F.R. 56347], except that any person marketing a food the brand name of which contains a term defined by the Secretary under section 403(r)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act shall be given an additional 6 months to comply with section 3,

''(C) the amendments made by section 4 [amending section 337 of this title] shall take effect 24 months after the date of the enactment of this Act [Nov. 8, 1990], except that such amendments shall take effect with respect to such dietary supplements [probably means dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 202(a)(1) of Pub. L. 102–571, set out below] on December 31, 1993, and

''(D) the amendments made by section 5 [amending sections 321 and 345 of this title] shall take effect on

the date the amendments made by section 3 take effect.

''(2) Section 403(q) of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 2 and section 403(r) of the Federal Food, Drug, and Cosmetic Act (as added by section 3) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 3.

''(3)(A) If the Secretary finds that a person who is subject to section 403(q)(4) of such Act is unable to comply with the requirements of such section upon the effective date of final regulations to implement section 403(q) of such Act or of proposed regulations to be considered as such final regulations because the Secretary has not made available to such person the information required by such section, the Secretary shall delay the application of such section to such person for such time as the Secretary may require to provide such information.

''(B) If the Secretary finds that compliance with section 403(q) or 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year.''

Section 10(c) of Pub. L. 101–535, as amended by Pub. L. 102–108, §1, Aug. 17, 1991, 105 Stat. 549; Pub. L. 102–571, title I, §107(17), Oct. 29, 1992, 106 Stat. 4500, provided that:

''(1) Except as provided in paragraphs (2) and (3), the amendments made by section 7 [amending this section] shall take effect one year after the date of the enactment of this Act [Nov. 8, 1990].

''(2)(A) If a food subject to section 403(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(g)] or a food with one or more colors required to be certified under section 721(c) [of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 379e(c)] bears a label which was printed before July 1, 1991, and which is attached to the food before May 8, 1993, such food shall not be subject to the amendments made by section 7(1) and section 7(3) [amending this section].

''(B) If a food described in subparagraph (A)—

''(i) bears a label which was printed after July 1, 1991, but before the date the proposed regulation described in clause (ii) takes effect as a final regulation and which was attached to the food before May 8, 1993, and

''(ii) meets the requirements of the proposed regulation of the Secretary of Health and Human Services published in 56 Fed. Reg. 28592–28636 (June 21, 1991) as it pertains to the amendments made by this Act [see Short Title of 1990 Amendment note set out under section 301 of this title],

such food shall not be subject to the amendments made by section 7(1) and section 7(3) [amending this section].

''(3) A food purported to be a beverage containing a vegetable or fruit juice which bears a label attached to the food before May 8, 1993, shall not be subject to the amendments made by section 7(2) [amending this section].''

EFFECTIVE DATE OF 1977 AMENDMENT

Section 4(a)(2) of Pub. L. 95–203 provided that: ''The amendment made by paragraph (1) [amending this section] shall apply only with respect to food introduced or delivered for introduction in interstate commerce on and after the 90th day after the date of the enactment of this Act [Nov. 23, 1977].''

Section 4(b)(2) of Pub. L. 95–203 provided that: ''The amendment made by paragraph (1) [amending this section] shall apply with respect to food which is sold in retail establishments on or after the 90th day after the effective date of the regulations of the Secretary of Health, Education, and Welfare [now Secretary of Health and Human Services] under paragraph (p)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(p)(4)].''

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94–278, set out as a note under section 334 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsecs. (e)(1) and (g) to (k) effective Jan. 1, 1940, and such subsections effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

REGULATIONS

Section 2(b) of Pub. L. 101–535, as amended by Pub. L. 102–571, title II, §202(a)(2)(A), (B), Oct. 29, 1992, 106 Stat. 4500, 4501, provided that:

''(1) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)] within 12 months after the date of the enactment of this Act [Nov. 8, 1990], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement the requirements of such section, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances..[sic] Such regulations shall—

''(A) require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet,

''(B) include regulations which establish standards, in accordance with paragraph (1)(A), to define serving size or other unit of measure for food,

''(C) permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

''(D) permit the nutrition information on the label or labeling of a food to remain the same or permit the information to be stated as a range even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

''(2) If the Secretary of Health and Human Services does not promulgate final regulations under paragraph (1) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1) shall be considered as the final regulations upon the expiration of such 24 months, except that the proposed regulations applicable to dietary supplements of vitamins, min-

erals, herbs, or other similar nutritional substances shall not be considered to be final regulations until December 31, 1993. There shall be promptly published in the Federal Register notice of new status of the proposed regulations [see 57 F.R. 56347].

''(3) If the Secretary of Health and Human Services does not promulgate final regulations under section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act upon the expiration of 6 months after the date on which the Secretary makes a finding that there has been no substantial compliance with section 403(q)(4)(C) of such Act, the proposed regulations issued in accordance with such section shall be considered as the final regulations upon the expiration of such 6 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations.''

[Section 202(a)(2)(C) of Pub. L. 102–571 provided that: ''The amendments made by subparagraph (B) [amending sections 2(b) and 3(b) of Pub. L. 101–535, set out above and below] shall not be construed to modify the effective date of final regulations under sections 2(b) and 3(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535] (21 U.S.C. 343 note) with respect to foods that are not such dietary supplements.'']

Section 3(b) of Pub. L. 101–535, as amended by Pub. L. 102–571, title II, § 202(a)(2)(A), (B), Oct. 29, 1992, 106 Stat. 4500, 4501, provided that:

''(1)(A) Within 12 months of the date of the enactment of this Act [Nov. 8, 1990], the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(r)], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Such regulations—

''(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

''(ii) shall identify claims described in section 403(r)(1)(B) of such Act which comply with section 403(r)(3) of such Act,

''(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

''(I) free,

''(II) low,

''(III) light or lite,

''(IV) reduced,

''(V) less, and

''(VI) high,

unless the Secretary finds that the use of any such term would be misleading,

''(iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act,

''(v) shall provide that if multiple claims subject to section 403(r)(1)(A) of such Act are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy section 403(r)(2)(B) of such Act,

''(vi) shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

''(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim,

''(viii) may permit a claim described in section 403(r)(1)(A) of such Act to be made for butter,

''(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

''(x) shall establish, as required by section 403(r)(5)(D), the procedure and standard respecting the validity of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxident [sic] vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

''(B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances..[sic]

''(2) If the Secretary does not promulgate final regulations under paragraph (1)(B) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1)(A) shall be considered as the final regulations upon the expiration of such 24 months, except that the proposed regulations applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not be considered to be final regulations until December 31, 1993. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations [see 57 F.R. 56347].''

[For construction of amendment made by section 202(a)(2)(B) of Pub. L. 102–571 to section 3(b) of Pub. L. 101–535 set out above, see section 202(a)(2)(C) of Pub. L. 102–571 set out above following section 2(b) of Pub. L. 101–535.]

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101–535

Section 9 of Pub. L. 101–535 provided that: ''The amendments made by this Act [enacting section 343–1 of this title and amending this section and sections 321, 337, 345, and 371 of this title] shall not be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], the Federal Meat Inspection Act [21 U.S.C. 601 et seq.], the Poultry Products Inspection Act [21 U.S.C. 451 et seq.], and the Egg Products Inspection Act [21 U.S.C. 1031 et seq.].''

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

COMMISSION ON DIETARY SUPPLEMENT LABELS

Section 12 of Pub. L. 103–417 provided that:

''(a) ESTABLISHMENT.—There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the 'Commission').

''(b) MEMBERSHIP.—

''(1) COMPOSITION.—The Commission shall be composed of 7 members who shall be appointed by the President.

''(2) EXPERTISE REQUIREMENT.—The members of the Commission shall consist of individuals with expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacog-

nosy, medical botany, traditional herbal medicine, or other related sciences. Members and staff of the Commission shall be without bias on the issue of dietary supplements.

''(c) FUNCTIONS OF THE COMMISSION.—The Commission shall conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

''(d) ADMINISTRATIVE POWERS OF THE COMMISSION.—

''(1) HEARINGS.—The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.

''(2) INFORMATION FROM FEDERAL AGENCIES.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

''(e) REPORTS AND RECOMMENDATIONS.—

''(1) FINAL REPORT REQUIRED.—Not later than 24 months after the date of enactment of this Act [Oct. 25, 1994], the Commission shall prepare and submit to the President and to the Congress a final report on the study required by this section.

''(2) RECOMMENDATIONS.—The report described in paragraph (1) shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate.

''(3) ACTION ON RECOMMENDATIONS.—Within 90 days of the issuance of the report under paragraph (1), the Secretary of Health and Human Services shall publish in the Federal Register a notice of any recommendation of Commission for changes in regulations of the Secretary for the regulation of dietary supplements and shall include in such notice a notice of proposed rulemaking on such changes together with an opportunity to present views on such changes. Such rulemaking shall be completed not later than 2 years after the date of the issuance of such report. If such rulemaking is not completed on or before the expiration of such 2 years, regulations of the Secretary published in 59 FR 395–426 on January 4, 1994, shall not be in effect.''

EXTENSION OF COMPLIANCE DEADLINE FOR CERTAIN FOOD PRODUCTS PACKAGED PRIOR TO AUGUST 8, 1994

Pub. L. 103–261, May 26, 1994, 108 Stat. 705, provided: ''That before August 8, 1994, sections 403(q) and 403(r)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q), (r)(2)] and the provision of section 403(i) of such Act added by section 7(2) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535], shall not apply with respect to a food product which is contained in a package for which the label was printed before May 8, 1994 (or before August 8, 1994, in the case of a juice or milk food product if the person responsible for the labeling of such food product exercised due diligence in obtaining before such date labels which are in compliance with such sections 403(q) and 403(r)(2) and such provision of section 403(i)), if, before June 15, 1994, the person who introduces or delivers for introduction such food product into interstate commerce submits to the Secretary of Health and Human Services a certification that such person will comply with this section and will comply with such sections 403(q) and 403(r)(2) and such provision of section 403(i) after August 8, 1994.''

LIMITATIONS ON APPLICATION OF SMALL BUSINESS EXEMPTION

Section 2(a) of Pub. L. 103–80 provided that:

''(1) BEFORE MAY 8, 1995.—Before May 8, 1995, the exemption provided by section 403(q)(5)(D) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(D)] shall be available in accordance with the regulations of the Secretary of Health and Human Services published at 21 C.F.R. 101.9(j)(1)(i)(1993).

''(2) AFTER MAY 8, 1995.—After May 8, 1995, the exemption provided by section 403(q)(5)(D) of the Federal Food, Drug, and Cosmetic Act shall only be available with respect to food when it is sold to consumers.''

PROHIBITION ON IMPLEMENTATION OF PUB. L. 101–535 WITH RESPECT TO DIETARY SUPPLEMENTS

Section 202(a)(1) of Pub. L. 102–571 provided that: ''Notwithstanding any other provision of law and except as provided in subsection (b) [set out as a note below] and in the amendment made by paragraph (2)(A) [amending provisions set out as notes above], the Secretary of Health and Human Services may not implement the Nutrition Labeling and Education Act of 1990 (Public Law 101–535; 104 Stat. 2353) [see Short Title of 1990 Amendments note set out under section 301 of this title], or any amendment made by such Act, earlier than December 15, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.''

HEALTH CLAIMS MADE WITH RESPECT TO DIETARY SUPPLEMENTS

Section 202(b) of Pub. L. 102–571 provided that: ''Notwithstanding section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(5)(D)) and subsection (a) [enacting provisions set out as notes above and amending provisions set out as notes above and under section 343–1 of this title], the Secretary of Health and Human Services may, earlier than December 15, 1993, approve claims made with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535] (21 U.S.C. 343 note).''

UNITED STATES RECOMMENDED DAILY ALLOWANCES OF VITAMINS OR MINERALS

Section 203 of Pub. L. 102–571 provided that: ''Notwithstanding any other provision of Federal law, no regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals may be promulgated before November 8, 1993 (other than regulations establishing the United States recommended daily allowances specified at section 101.9(c)(7)(iv) of title 21, Code of Federal Regulations, as in effect on October 6, 1992, or regulations under section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)(A)) that are based on such recommended daily allowances).''

CONSUMER EDUCATION

Section 2(c) of Pub. L. 101–535 provided that: ''The Secretary of Health and Human Services shall carry out activities which educate consumers about—

''(1) the availability of nutrition information in the label or labeling of food, and

''(2) the importance of that information in maintaining healthy dietary practices.''

STUDIES CONCERNING CARCINOGENIC AND OTHER TOXIC SUBSTANCES IN FOOD AND IMPURITIES IN AND TOXICITY OF SACCHARIN

Section 2 of Pub. L. 95–203 directed Secretary of Health, Education, and Welfare to conduct a study concerning carcinogenic and other toxic substances in food and impurities in and toxicity of saccharin and make a report respecting the carcinogenic and other sub-

stances to Committee on Human Resources of the Senate within 12 months of Nov. 23, 1977, and a report respecting saccharin to such committee within 15 months of Nov. 23, 1977.

REPORT TO CONGRESSIONAL COMMITTEES RESPECTING ACTION TAKEN PURSUANT TO SUBSEC. (*o*)(2)

Section 4(a)(3) of Pub. L. 95–203 provided that: ''The Secretary shall report to the Committee on Human Resources of the Senate [now the Committee on Labor and Human Resources of the Senate] and the Committee on Interstate and Foreign Commerce [now the Committee on Commerce] of the House of Representatives any action taken under section 403(*o*)(2) of the Federal Food, Drug, and Cosmetic Act [par. (*o*)(2) of this section].''

STATE OR TERRITORIAL REQUIREMENTS

Section 2 of Pub. L. 86–537 provided that: ''Nothing in the amendments made by the first section of this Act [amending this section] shall affect any requirement of the laws of any State or Territory.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 337, 343–1, 345, 347, 350, 371 of this title.

### § 343–1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), or 343(i)(2) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

(June 25, 1938, ch. 675, § 403A, as added Nov. 8, 1990, Pub. L. 101–535, § 6(a), 104 Stat. 2362; amended Aug. 17, 1991, Pub. L. 102–108, § 2(b), 105 Stat. 549; Oct. 22, 1994, Pub. L. 103–396, § 3(a), 108 Stat. 4154.)

REFERENCES IN TEXT

Section 6(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535], referred to in subsec. (a), is set out below.

AMENDMENTS

1994—Subsec. (a)(1). Pub. L. 103–396, § 3(a)(1), inserted at end ''except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,''.

Subsec. (a)(2). Pub. L. 103–396, § 3(a)(2), inserted at end ''except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,''.

Subsec. (a)(3). Pub. L. 103–396, § 3(a)(3), inserted at end ''except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,''.

1991—Subsec. (a)(5). Pub. L. 102–108 substituted ''section 343(r)(5)(B) of this title'' for ''clause (B) of such section''.

EFFECTIVE DATE

Section 10(b) of Pub. L. 101–535, as amended by Pub. L. 102–571, title I, § 107(16), title II, § 202(a)(4), Oct. 29, 1992, 106 Stat. 4499, 4501, provided that:

''(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by section 6 [enacting this section] shall take effect—

''(A) with respect to a requirement of a State or political subdivision described in paragraph (1) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act [subsec. (a)(1) of this section], on the date of the enactment of this Act [Nov. 8, 1990],

''(B) with respect to a requirement of a State or political subdivision described in paragraph (2) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, one year after the date of the enactment of this Act,

''(C) with respect to a requirement of a State or political subdivision described in paragraph (3) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, as prescribed by section 6(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535, set out below],

''(D) with respect to a requirement of a State or political subdivision described in paragraph (4) of sec-

tion 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(q) of such Act [21 U.S.C. 343(q)] take effect, and

''(E) with respect to a requirement of a State or political subdivision described in paragraph (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(r) of such Act take effect.

''(2) EXCEPTION.—If a State or political subdivision submits a petition under section 403A(b) of the Federal Food, Drug, and Cosmetic Act for a requirement described in section 403A(a) of such Act within 18 months of the date of the enactment of this Act, paragraphs (3) through (5) of such section 403A(a) shall not apply with respect to such State or political subdivision requirement until—

''(A) 24 months after the date of the enactment of this Act, or

''(B) action on the petition,

whichever occurs later.

''(3) REQUIREMENTS PERTAINING TO CERTAIN CLAIMS.—Notwithstanding subparagraphs (D) and (E) of paragraph (1) and except with respect to claims approved in accordance with section 202(b) of the Dietary Supplement Act of 1992 [Pub. L. 102–571, set out as a note under section 343 of this title], the requirements described in paragraphs (4) and (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(4) and (5)) that pertain to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not take effect until the date final regulations take effect to implement subsection (q) or (r), as appropriate, of section 403 of such Act with respect to such dietary supplements.''

Section 6(b) of Pub. L. 101–535 provided that:

''(1) For the purpose of implementing section 403A(a)(3) [21 U.S.C. 343–1(a)(3)], the Secretary of Health and Human Services shall enter into a contract with a public or nonprofit private entity to conduct a study of—

''(A) State and local laws which require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(b), (d), (f), (h), (i)(1), (k)], and

''(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

''(2) The contract under paragraph (1) shall provide that the study required by such paragraph shall be completed within 6 months of the date of the enactment of this Act [Nov. 8, 1990].

''(3)(A) Within 9 months of the date of the enactment of this Act, the Secretary shall publish a proposed list of sections which are adequately being implemented by regulations as determined under paragraph (1)(B) and sections which are not adequately being implemented by regulations as so determined. After publication of the lists, the Secretary shall provide 60 days for comments on such lists.

''(B) Within 24 months of the date of the enactment of this Act, the Secretary shall publish a final list of sections which are adequately being implemented by regulations and a list of sections which are not adequately being implemented by regulations. With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to the requirement of such section.

''(C) Within 24 months of the date of the enactment of this Act, the Secretary shall publish proposed revisions to the regulations found to be inadequate under subparagraph (B) and within 30 months of such date shall issue final revisions. Upon the effective date of such final revisions, no State or political subdivision may establish or continue in effect any requirement which is not identical to the requirement of the section which had its regulations revised in accordance with this subparagraph.

''(D)(i) If the Secretary does not issue a final list in accordance with subparagraph (B), the proposed list issued under subparagraph (A) shall be considered the final list and States and political subdivisions shall be preempted with respect to sections found to be adequate in such proposed list in accordance with subparagraph (B).

''(ii) If the Secretary does not issue final revisions of regulations in accordance with subparagraph (C), the proposed revisions issued under such subparagraph shall be considered the final revisions and States and political subdivisions shall be preempted with respect to sections the regulations of which are revised by the proposed revisions.

''(E) Subsection (b) of section 403A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the prohibition prescribed by subparagraphs (B) and (C).''

CONSTRUCTION OF PUB. L. 101–535

Section 6(c) of Pub. L. 101–535 provided that:

''(1) The Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535, see Short Title of 1990 Amendment note set out under section 301 of this title] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act [this section].

''(2) The amendment made by subsection (a) [enacting this section] and the provisions of subsection (b) [set out as a note above] shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

''(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act [this chapter] not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.''

Amendments by Pub. L. 101–535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101–535, set out as a note under section 343 of this title.

DELAYED APPLICABILITY OF CERTAIN PROVISIONS

Pub. L. 102–408, title III, § 310, Oct. 13, 1992, 106 Stat. 2090, provided that: ''Notwithstanding any other provision of law, section 403A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(1)) shall not apply with respect to any requirement of any State or political subdivision regarding maple syrup until September 1, 1994.''

## § 343–2. Dietary supplement labeling exemptions

### (a) In general

A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

**(b) Application**

Subsection (a) of this section shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

**(c) Burden of proof**

In any proceeding brought under subsection (a) of this section, the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

(June 25, 1938, ch. 675, § 403B, as added Oct. 25, 1994, Pub. L. 103–417, § 5, 108 Stat. 4328.)

### § 343a. Health risks presented by use of saccharin

**(a) Statement on vending machines dispensing food containing saccharin respecting health risk; regulations**

The Secretary may by regulation require vending machines through which food containing saccharin is sold to bear a statement of the risks to health which may be presented by the use of saccharin. A regulation under this subsection shall require such statement to be located in a conspicuous place on such vending machine and as proximate as possible to the name of each food containing saccharin which is sold through such machine. Any food containing saccharin which is sold in a vending machine which does not meet any applicable requirement promulgated under this subsection shall, for purposes of this chapter, be considered a misbranded food.

**(b) Availability and distribution of information; review and revision**

The Secretary shall (1) prepare information respecting the nature of the controversy surrounding the use of food containing saccharin, and (2) provide for the distribution of such information for display by retail establishments where such food is sold but not for immediate consumption. The Secretary may review and revise such information if he determines such action is necessary to reflect the current state of knowledge concerning the risks to health presented by the use of saccharin.

(Pub. L. 95–203, § 4(c), (d), Nov. 23, 1977, 91 Stat. 1453, 1454.)

CODIFICATION

Subsecs. (a) and (b) of this section were, in the original, designated as ''(c)'' and ''(d)'' and have been editorially changed for codification purposes.

Section was enacted as part of Pub. L. 95–203, known as the Saccharin Study and Labeling Act and not as part of act June 25, 1938, ch. 675, 52 Stat. 1040, known as the Federal Food, Drug, and Cosmetic Act, which comprises this chapter.

### § 344. Emergency permit control

**(a) Conditions on manufacturing, processing, etc., as health measure**

Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

**(b) Violation of permit; suspension and reinstatement**

The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

**(c) Inspection of permit-holding establishments**

Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

(June 25, 1938, ch. 675, § 404, 52 Stat. 1048.)

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 334, 371 of this title.

### § 345. Regulations making exemptions

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment. This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title.

(June 25, 1938, ch. 675, § 405, 52 Stat. 1049; Nov. 8, 1990, Pub. L. 101–535, § 5(a), 104 Stat. 2362.)

AMENDMENTS

1990—Pub. L. 101–535 inserted at end ''This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title.''

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101–535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101–535

Amendments by Pub. L. 101–535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101–535, set out as a note under section 343 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title.

### § 346. Tolerances for poisonous or deleterious substances in food; regulations

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(June 25, 1938, ch. 675, § 406, 52 Stat. 1049; Sept. 6, 1958, Pub. L. 85–929, § 3(c), 72 Stat. 1785; July 12, 1960, Pub. L. 86–618, title I, § 103(a)(1), 74 Stat. 398.)

AMENDMENTS

1960—Pub. L. 86–618 repealed subsec. (b) which required Secretary to promulgate regulations for listing of coal-tar colors.

1958—Subsec. (a). Pub. L. 85–929 substituted ''clause (2)(A)'' for ''clause (2)'' in first sentence.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86–139, Aug. 7, 1959, 73 Stat. 288.

EFFECTIVE DATE OF 1958 AMENDMENT

For effective date of amendment by Pub. L. 85–929, see section 6(b), (c) of Pub. L. 85–929, set out as a note under section 342 of this title.

TRANSFER OF FUNCTIONS

Functions vested in Secretary of Health, Education, and Welfare [now Health and Human Services] in establishing tolerances for pesticide chemicals under this section together with authority to monitor compliance with tolerances and effectiveness of surveillance and enforcement and to provide technical assistance to States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, transferred to Administrator of Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see note set out under section 41 of this title.

CROSS REFERENCES

Pesticide chemical regulations, see section 346a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 342, 346a, 371 of this title.

### § 346a. Tolerances for pesticide chemicals in or on raw agricultural commodities

**(a) Conditions of safety**

Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 342(a) of this title unless—

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Administrator of the Environmental Protection Agency (hereinafter in this section referred to as the ''Administrator'') under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Administrator under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title.

**(b) Establishment of tolerances**

The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture[1] as submitted with a certification of usefulness under subsection (*l*) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Administrator may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Administrator does not justify the establishment of a greater tolerance.

[1] See Transfer of Functions note below.

**(c) Exemptions**

The Administrator shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

**(d) Regulations pursuant to petition; publication of notice; time for issuance; referral to advisory committees; effective date; hearings**

(1) Any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] may file with the Administrator of Health and Human Services,[2] a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such pesticide, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Administrator upon request. Notice of the filing of such petition shall be published in general terms by the Administrator within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture[3] under subsection (*l*) of this section with respect to the pesticide chemical named in the petition, the Administrator of Health and Human Services[4] shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Ad-

[2] So in original. The words ''of Health and Human Services,'' probably should not appear.

[3] See Transfer of Functions note below.

[4] So in original. The words ''Health and Human Services'' probably should not appear.

ministrator within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture[3] under subsection (*l*) of this section with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Administrator of Health and Human Services[4] within such period otherwise deems such referral necessary, the Administrator of Health and Human Services[4] shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal in the petition to the Administrator, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e) of this section, may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Administrator shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 556(c)[5] of title 5. The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Administrator, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Administrator shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

**(e) Regulations pursuant to Administrator's proposals**

The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Administrator may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Administrator shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d) of this section.

[5] So in original. Probably should be section "556(d)".

**(f) Data submitted as confidential**

All data submitted to the Administrator or to an advisory committee in support of a petition under this section shall be considered confidential by the Administrator and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Administrator or by an advisory committee in the carrying out of their official duties under this section.

**(g) Advisory committees; appointment; composition; compensation; clerical assistance**

Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Administrator otherwise deems such referral necessary the Administrator shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Administrator. Members of an advisory committee shall receive compensation and travel expenses in accordance with subsection (b)(5)(D) of section 379e of this title. The members shall not be subject to any other provision of law regarding the appointment and compensation of employees of the United States. The Administrator shall furnish the Committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

**(h) Right of consultation**

A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provisions of this section, as well as representatives of the Department of Health and Human Services, shall have the right to consult with any advisory committee provided for in subsection (g) of this section in connection with the petition or proposal.

**(i) Judicial review**

(1) In a case of actual controversy as to the validity of any order under subsection (d)(5), (e), or (*l*) of this section any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d)(5) or (e) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (*l*) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture,[6] or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Administrator of Health and Human Services[7] or the Secretary of Agriculture,[6] as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Administrator of Health and Human Services[7] or the Secretary of Agriculture,[6] as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

**(j) Temporary tolerances**

The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Administrator shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the

[6] See Transfer of Functions note below.

[7] So in original. The words ''Health and Human Services'' probably should not appear.

public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

**(k) Regulations based on public hearings before January 1, 1953**

Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 346(a) of this title upon the basis of public hearings instituted before January 1, 1953, in accordance with section 371(a) of this title, shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m) of this section.

**(*l*) Pesticides under Federal Insecticide, Fungicide, and Rodenticide Act; functions of Administrator of the Environmental Protection Agency; certifications; hearing; time limitation; opinion; regulations**

The Secretary of Agriculture,[8] upon request of any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) of this section with respect to a pesticide chemical which constitutes, or is an ingredient of, such pesticide, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Administrator deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify to the Administrator of Health and Human Services[9] that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture[8] takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture[8] to certify to the Administrator of Health and Human Services[9] on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Administrator may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Administrator shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Secretary of Agriculture[8] shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture[8] as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture[8] exceed one hundred and sixty days. The Administrator shall submit to the Administrator of Health and Human Services[9] with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture,[8] after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

**(m) Amendment of regulations**

The Administrator of Health and Human Services[9] shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

**(n) Guaranties**

The provisions of section 333(c) of this title with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

**(*o*) Payment of fees; services or functions as conditioned on; waiver or refund of fees**

The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's[10] functions under this section. Under such regulations, the performance of the Secretary's[10] services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d) of this section; (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d)(5) of this section; or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i)(2) of this section. Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such waiver or refund

[8] See Transfer of Functions note below.

[9] So in original. The words ''Health and Human Services'' probably should not appear.

[10] So in original. Probably should be ''Administrator's''.

is equitable and not contrary to the purposes of this subsection.

(June 25, 1938, ch. 675, § 408, as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; amended Aug. 28, 1958, Pub. L. 85–791, § 20, 72 Stat. 947; Oct. 30, 1970, Pub. L. 91–515, title VI, § 601(d)(1), 84 Stat. 1311; Nov. 18, 1971, Pub. L. 92–157, title III, § 303(a), 85 Stat. 464; Oct. 21, 1972, Pub. L. 92–516, § 3(3), 86 Stat. 998; Nov. 8, 1984, Pub. L. 98–620, title IV, § 402(25)(A), 98 Stat. 3359; June 16, 1992, Pub. L. 102–300, § 6(b)(1), 106 Stat. 240; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(7), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103–80, § 3(k), 107 Stat. 776.)

REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsecs. (d)(1), (e), (j), and (*l*), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

AMENDMENTS

1993—Pub. L. 103–80, § 3(k)(6), substituted ''Administrator'' for ''Secretary'' wherever appearing except when followed by ''of Agriculture''.

Subsec. (a)(1). Pub. L. 103–80, § 3(k)(1), substituted ''Administrator of the Environmental Protection Agency (hereinafter in this section referred to as the 'Administrator')'' for ''Secretary of Health and Human Services''.

Subsec. (d)(5). Pub. L. 103–80, § 3(k)(2), substituted ''section 556(c) of title 5'' for ''section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))''.

Subsec. (*l*). Pub. L. 103–80, § 3(k)(3), substituted ''In the event'' for ''It the event'' before ''a hearing is requested''.

Subsec. (n). Pub. L. 103–80, § 3(k)(4), made technical amendment to reference to section 333(c) of this title to reflect amendment of corresponding provision of original act.

Subsec. (*o*). Pub. L. 103–80, § 3(k)(5), which directed the substitution of ''Administrator'' for ''Secretary of Health and Human Services'' wherever appearing in the original text, was executed by making the substitution in the first sentence before ''shall by regulation require'', the only place ''Secretary of Health and Human Services'' appeared in the original text.

1992—Subsecs. (a), (d), (h), (i), (*l*), (m), (*o*). Pub. L. 102–300 substituted ''Health and Human Services'' for ''Health, Education, and Welfare'' wherever appearing in the original statutory text.

Subsec. (g). Pub. L. 102–571 substituted ''379e'' for ''376''.

1984—Subsec. (i)(5). Pub. L. 98–620 struck out provision that required the court to advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

1972—Subsecs. (d)(1), (e), (*l*). Pub. L. 92–516 substituted references to pesticide for references to economic poison wherever appearing therein.

1971—Subsec. (g). Pub. L. 92–157 struck out '', which the Secretary shall by rules and regulations prescribe,'' after ''as compensation for their services a reasonable per diem'' prior to amendment in 1970, by Pub. L. 91–515, which overlooked such language when amending subsec. (g) as provided in 1970 Amendment note.

1970—Subsec. (g). Pub. L. 91–515 substituted provisions authorizing members of an advisory committee to receive compensation and travel expenses in accordance with section 376(b)(5)(D) of this title, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1958—Subsec. (i)(2). Pub. L. 85–791, § 20(a), in first sentence, substituted ''transmitted by the clerk of the court to the Secretary, or'' for ''served upon the Secretary, or upon'', substituted ''file in the court the record of the proceedings'' for ''certify and file in the court a transcript of the proceedings and the record'', and inserted ''as provided in section 2112 of title 28'', and which, in second sentence, substituted ''the filing of such petition'' for ''such filing''.

Subsec. (i)(3). Pub. L. 85–791, § 20(b), in first sentence, substituted ''transmitted by the clerk of the court to the Secretary of Agriculture, or'' for ''served upon the Secretary of Agriculture, or upon'', substituted ''file in the court the record of the proceedings'' for ''certify and file in the court a transcript of the proceedings and the record'', and inserted ''as provided in section 2112 of title 28'', and, in second sentence, substituted ''the filing of such petition'' for ''such filing''.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–516 effective at close of Oct. 21, 1972, except if regulations are necessary for implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, Agriculture, and regulations thereunder, relating to control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92–516 and regulations thereunder, see section 4 of Pub. L. 92–516, set out as an Effective Date note under section 136 of Title 7.

TRANSFER OF FUNCTIONS

Functions vested in Secretary of Health, Education, and Welfare [now Health and Human Services] in establishing tolerances for pesticide chemicals under this section together with authority to monitor compliance with tolerances and effectiveness of surveillance and enforcement and to provide technical assistance to States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, and functions of Department of Agriculture and Secretary of Agriculture under subsec. (*l*) of this section transferred to Administrator of Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

CROSS REFERENCES

Federal Advisory Committee Act, see Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 342, 346b, 453, 601, 1033 of this title; title 7 section 450i.

## § 346b. Authorization of appropriations

There are authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purpose and administration of sections 321(q), (r), 342(a)(2), and 346a of this title.

(July 22, 1954, ch. 559, § 4, 68 Stat. 517.)

CODIFICATION

Section was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

## § 347. Intrastate sales of colored oleomargarine

### (a) Law governing

Colored oleomargarine or colored margarine which is sold in the same State or Territory in

which it is produced shall be subject in the same manner and to the same extent to the provisions of this chapter as if it had been introduced in interstate commerce.

**(b) Labeling and packaging requirements**

No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) such oleomargarine or margarine is packaged,

(2) the net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) there appears on the label of the package (A) the word ''oleomargarine'' or ''margarine'' in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine or margarine, and

(4) each part of the contents of the package is contained in a wrapper which bears the word ''oleomargarine'' or ''margarine'' in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this chapter.

**(c) Sales in public eating places**

No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

**(d) Exemption from labeling requirements**

Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this title (except paragraphs (a) and (f)) if it complies with the requirements of subsection (b) of this section.

**(e) Color content of oleomargarine**

For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent.

(June 25, 1938, ch. 675, § 407, as added Mar. 16, 1950, ch. 61, § 3(c), 64 Stat. 20.)

EFFECTIVE DATE

Section 7 of act Mar. 16, 1950, provided that: ''This Act [enacting this section and sections 347a and 347b of this title and amending sections 331 and 342 of this title and sections 45 and 55 of Title 15, Commerce and Trade] shall become effective on July 1, 1950.''

TRANSFER OF APPROPRIATIONS

Section 5 of act Mar. 16, 1950, provided that: ''So much of the unexpended balances of appropriations, allocations, or other funds (including funds available for the fiscal year ending June 30, 1950) for the use of the Bureau of Internal Revenue of the Treasury Department in the exercise of functions under the Oleomargarine Tax Act (26 U.S.C., § 2300, subchapter A) [now section 4591 et seq. of Title 26, Internal Revenue Code], as the Director of the Bureau of the Budget [now Director of the Office of Management and Budget] may determine, shall be transferred to the Federal Security Agency (Food and Drug Administration) [now the Department of Health and Human Services] for use in the enforcement of this Act [see Effective Date note above].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 347b of this title.

## § 347a. Congressional declaration of policy regarding oleomargarine sales

The Congress finds and declares that the sale, or the serving in public eating places, of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of this chapter depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded, and constitutes a burden on interstate commerce in such articles. Such burden exists, irrespective of whether such oleomargarine or margarine originates from an interstate source or from the State in which it is sold.

(Mar. 16, 1950, ch. 61, § 3(a), 64 Stat. 20.)

CODIFICATION

Section was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as a note under section 347 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 347b of this title.

## § 347b. Contravention of State laws

Nothing in this Act shall be construed as authorizing the possession, sale, or serving of colored oleomargarine or colored margarine in any State or Territory in contravention of the laws of such State or Territory.

(Mar. 16, 1950, ch. 61, § 6, 64 Stat. 22.)

REFERENCES IN TEXT

This Act, referred to in text, is act Mar. 16, 1950, ch. 61, 64 Stat. 20, which is classified to sections 331, 342, 347 to 347b of this title, and sections 45 and 55 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as a note under section 347 of this title.

## § 348. Food additives

### (a) Unsafe food additives; exception for conformity with exemption or regulation

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

### (b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation

(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

### (c) Approval or denial of petition; time for issuance of order; evaluation of data; factors

(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this chapter or would otherwise result in adulteration or in misbranding of food within the meaning of this chapter.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a

tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

**(d) Regulation issued on Secretary's initiative**

The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

**(e) Publication and effective date of orders**

Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f) of this section.

**(f) Objections and public hearing; basis and contents of order; statement**

(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

**(g) Judicial review**

(1) In a case of actual controversy as to the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

**(h) Amendment or repeal of regulations**

The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall

conform to the procedure provided in this section for the promulgation of such regulations.

**(i) Exemptions for investigational use**

Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(June 25, 1938, ch. 675, § 409, as added Sept. 6, 1958, Pub. L. 85–929, § 4, 72 Stat. 1785; amended June 29, 1960, Pub. L. 86–546, § 2, 74 Stat. 255; Oct. 10, 1962, Pub. L. 87–781, title I, § 104(f)(1), 76 Stat. 785; Nov. 8, 1984, Pub. L. 98–620, title IV, § 402(25)(B), 98 Stat. 3359.)

AMENDMENTS

1984—Subsec. (g)(2). Pub. L. 98–620 struck out provision that required the court to advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

1962—Subsec. (c)(3)(A). Pub. L. 87–781 excepted proviso from applying to use of a substance as an ingredient of feed for animals raised for food production, if under conditions of use specified in proposed labeling, and which conditions are reasonably certain to be followed in practice, such additive will not adversely affect the animals and no residue will be found in any edible portion of such animal after slaughter, or in any food from the living animal.

1960—Subsec. (g)(2). Pub. L. 86–546 substituted ''forthwith transmitted by the clerk of the court to the Secretary, or any officer'' for ''served upon the Secretary, or upon any officer'', ''shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28'' for ''shall certify and file in the court a transcript of the proceedings and the record on which he based his order'', and ''Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive,'' for ''Upon such filing, the court shall have exclusive jurisdiction'', and inserted sentence authorizing the Secretary to modify or set aside his order until the filing of the record.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

EFFECTIVE DATE

Section effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as an Effective Date of 1958 Amendment note under section 342 of this title.

TRANSFER OF FUNCTIONS

Functions vested in Secretary of Health, Education, and Welfare [now Health and Human Services] in establishing tolerances for pesticide chemicals under this section together with authority to monitor compliance with tolerances and effectiveness of surveillance and enforcement and to provide technical assistance to States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, transferred to Administrator of Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

MORATORIUM ON AUTHORITY OF SECRETARY WITH RESPECT TO SACCHARIN

Pub. L. 95–203, § 3, Nov. 23, 1977, 91 Stat. 1452, as amended by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 96–273, June 17, 1980, 94 Stat. 536; Pub. L. 97–42, § 2, Aug. 14, 1981, 95 Stat. 946; Pub. L. 98–22, § 2, Apr. 22, 1983, 97 Stat. 173; Pub. L. 99–46, May 24, 1985, 99 Stat. 81; Pub. L. 100–71, title I, § 101, July 11, 1987, 101 Stat. 431; Pub. L. 102–142, title VI, Oct. 28, 1991, 105 Stat. 910, provided that: ''During the period ending May 1, 1997, the Secretary—

''(1) may not amend or revoke the interim food additive regulation of the Food and Drug Administration of the Department of Health and Human Services applicable to saccharin and published on March 15, 1977 (section 180.37 of part 180, subchapter B, chapter 1, title 21, Code of Federal Regulations (42 Fed. Reg. 14638)), or

''(2) may, except as provided in section 4 [enacting section 343a of this title, amending sections 321 and 343 of this title, and enacting provisions set out as notes under section 343 of this title] and the amendments made by such section, not take any other action under the Federal Food, Drug, and Cosmetic Act [this chapter] to prohibit or restrict the sale or distribution of saccharin, any food permitted by such interim food additive regulation to contain saccharin, or any drug or cosmetic containing saccharin,

solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study made available to the Secretary before the date of the enactment of this Act [Nov. 23, 1977] which involved human studies or animal testing, or both.''

For definition of ''saccharin'' as used in this note, see section 2(d) of Pub. L. 95–203.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 379e, 453, 601, 1033 of this title; title 7 section 450i; title 15 section 1262; title 35 section 155.

## § 349. Bottled drinking water standards; publication in Federal Register

Whenever the Administrator of the Environmental Protection Agency prescribes interim or revised national primary drinking water regulations under section 300g–1 of title 42, the Secretary shall consult with the Administrator and within 180 days after the promulgation of such drinking water regulations either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register his reasons for not making such amendments.

(June 25, 1938, ch. 675, § 410, as added Dec. 16, 1974, Pub. L. 93–523, § 4, 88 Stat. 1694.)

## § 350. Vitamins and minerals

**(a) Authority and limitations of Secretary; applicability**

(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 321(n), 341, or 343 of this title, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 321(n), 341, or 343 of this title, the combination or number of any synthetic or natural—

(i) vitamin,

(ii) mineral, or

(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph,[1] the term ''children'' means individuals who are under the age of twelve years.

**(b) Labeling and advertising requirements for foods**

(1) A food to which this section applies shall not be deemed under section 343 of this title to be misbranded solely because its label bears, in accordance with section 343(i)(2) of this title, all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2) The labeling for any food to which this section applies may not list its ingredients which are not dietary supplement ingredients described in section 321(ff) of this title (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

**(c) Definitions**

(1) For purposes of this section, the term ''food to which this section applies'' means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 343(j) of this title insofar as that section is applicable to food to which this section applies, the term ''special dietary use'' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(June 25, 1938, ch. 675, § 411, as added Apr. 22, 1976, Pub. L. 94–278, title V, § 501(a), 90 Stat. 410; amended Oct. 25, 1994, Pub. L. 103–417, §§ 3(c), 7(d), 108 Stat. 4328, 4331.)

AMENDMENTS

1994—Subsec. (b)(2). Pub. L. 103–417, § 7(d), redesignated subpar. (A) as par. (2), substituted ''dietary supplement ingredients described in section 321(ff) of this title'' for ''vitamins or minerals'', and struck out former subpar. (B), which read as follows: ''Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

''(i) vitamins,

''(ii) minerals, or

''(iii) represented as a source of vitamins or minerals.''

Subsec. (c)(1)(B)(i). Pub. L. 103–417, § 3(c)(1), inserted ''powder, softgel, gelcap,'' after ''capsule,''.

Subsec. (c)(1)(B)(ii). Pub. L. 103–417, § 3(c)(2), struck out ''does not simulate and'' after ''in such a form,''.

EFFECTIVE DATE OF 1994 AMENDMENT

For provision that dietary supplements may be labeled after Oct. 25, 1994, in accordance with amendments made by section 7(d) of Pub. L. 103–417, and shall be so labeled after Dec. 31, 1996, see section 7(e) of Pub. L. 103–417, set out as a note under section 343 of this title.

AMENDMENT OF INCONSISTENT REGULATIONS BY SECRETARY

Section 501(b) of Pub. L. 94–278, as amended by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, provided that: ''The Secretary of Health and Human Services shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act [this chapter] which is inconsistent with section 411 of such Act [section 350 of this title] (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 343 of this title.

## § 350a. Infant formulas

**(a) Adulteration**

An infant formula, including an infant formula powder, shall be deemed to be adulterated if—

(1) such infant formula does not provide nutrients as required by subsection (i) of this section,

(2) such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1) of this section, or

(3) the processing of such infant formula is not in compliance with the good manufactur-

[1] So in original. Probably should be ''paragraph''.

ing practices and the quality control procedures prescribed by the Secretary under subsection (b)(2) of this section.

**(b) Requirements for quality factors, good manufacturing practices, and retention of records**

(1) The Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i) of this section.

(2)(A) The Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to assure that an infant formula provides nutrients in accordance with this subsection and subsection (i) of this section and is manufactured in a manner designed to prevent adulteration of the infant formula.

(B) The good manufacturing practices and quality control procedures prescribed by the Secretary under subparagraph (A) shall include requirements for—

(i) the testing, in accordance with paragraph (3) and by the manufacturer of an infant formula or an agent of such manufacturer, of each batch of infant formula for each nutrient required by subsection (i) of this section before the distribution of such batch,

(ii) regularly scheduled testing, by the manufacturer of an infant formula or an agent of such manufacturer, of samples of infant formulas during the shelf life of such formulas to ensure that such formulas are in compliance with this section,

(iii) in-process controls including, where necessary, testing required by good manufacturing practices designed to prevent adulteration of each batch of infant formula, and

(iv) the conduct by the manufacturer of an infant formula or an agent of such manufacturer of regularly scheduled audits to determine that such manufacturer has complied with the regulations prescribed under subparagraph (A).

In prescribing requirements for audits under clause (iv), the Secretary shall provide that such audits be conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula.

(3)(A) At the final product stage, each batch of infant formula shall be tested for vitamin A, vitamin B1, vitamin C, and vitamin E to ensure that such infant formula is in compliance with the requirements of this subsection and subsection (i) of this section relating to such vitamins.

(B) Each nutrient premix used in the manufacture of an infant formula shall be tested for each relied upon nutrient required by subsection (i) of this section which is contained in such premix to ensure that such premix is in compliance with its specifications or certifications by a premix supplier.

(C) During the manufacturing process or at the final product stage and before distribution of an infant formula, an infant formula shall be tested for all nutrients required to be included in such formula by subsection (i) of this section for which testing has not been conducted pursuant to subparagraph (A) or (B). Testing under this subparagraph shall be conducted to—

(i) ensure that each batch of such infant formula is in compliance with the requirements of subsection (i) of this section relating to such nutrients, and

(ii) confirm that nutrients contained in any nutrient premix used in such infant formula are present in each batch of such infant formula in the proper concentration.

(D) If the Secretary adds a nutrient to the list of nutrients in the table in subsection (i) of this section, the Secretary shall by regulation require that the manufacturer of an infant formula test each batch of such formula for such new nutrient in accordance with subparagraph (A), (B), or (C).

(E) For purposes of this paragraph, the term ''final product stage'' means the point in the manufacturing process, before distribution of an infant formula, at which an infant formula is homogenous and is not subject to further degradation.

(4)(A) The Secretary shall by regulation establish requirements respecting the retention of records. Such requirements shall provide for—

(i) the retention of all records necessary to demonstrate compliance with the good manufacturing practices and quality control procedures prescribed by the Secretary under paragraph (2), including records containing the results of all testing required under paragraph (2)(B),

(ii) the retention of all certifications or guarantees of analysis by premix suppliers,

(iii) the retention by a premix supplier of all records necessary to confirm the accuracy of all premix certifications and guarantees of analysis,

(iv) the retention of—

(I) all records pertaining to the microbiological quality and purity of raw materials used in infant formula powder and in finished infant formula, and

(II) all records pertaining to food packaging materials which show that such materials do not cause an infant formula to be adulterated within the meaning of section 342(a)(2)(C) of this title,

(v) the retention of all records of the results of regularly scheduled audits conducted pursuant to the requirements prescribed by the Secretary under paragraph (2)(B)(iv), and

(vi) the retention of all complaints and the maintenance of files with respect to, and the review of, complaints concerning infant formulas which may reveal the possible existence of a hazard to health.

(B)(i) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the expiration of the shelf life of such infant formula. Except as provided in clause (ii), such records shall be made available to the Secretary for review and duplication upon request of the Secretary.

(ii) A manufacturer need only provide written assurances to the Secretary that the regularly scheduled audits required by paragraph (2)(B)(iv)

are being conducted by the manufacturer, and need not make available to the Secretary the actual written reports of such audits.

**(c) Registration of persons distributing new infant formula**

(1) No person shall introduce or deliver for introduction into interstate commerce any new infant formula unless—

(A) such person has, before introducing such new infant formula, or delivering such new infant formula for introduction, into interstate commerce, registered with the Secretary the name of such person, the place of business of such person, and all establishments at which such person intends to manufacture such new infant formula, and

(B) such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection (c)(1) of this section.

(2) For purposes of paragraph (1), the term ''new infant formula'' includes—

(A) an infant formula manufactured by a person which has not previously manufactured an infant formula, and

(B) an infant formula manufactured by a person which has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer.

For purposes of this paragraph, the term ''major change'' has the meaning given to such term in section 106.30(c)(2) of title 21, Code of Federal Regulations (as in effect on August 1, 1986), and guidelines issued thereunder.

**(d) Submission of information about new infant formula required**

(1) A person shall, with respect to any infant formula subject to subsection (c) of this section, make a submission to the Secretary which shall include—

(A) the quantitative formulation of the infant formula,

(B) a description of any reformulation of the formula or change in processing of the infant formula,

(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b)(1) and (i) of this section, as demonstrated by the testing required under subsection (b)(3) of this section, and

(D) assurances that the processing of the infant formula complies with subsection (b)(2) of this section.

(2) After the first production of an infant formula subject to subsection (c) of this section, and before the introduction into interstate commerce of such formula, the manufacturer of such formula shall submit to the Secretary, in such form as may be prescribed by the Secretary, a written verification which summarizes test results and records demonstrating that such formula complies with the requirements of subsections (b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (i) of this section.

(3) If the manufacturer of an infant formula for commercial or charitable distribution for human consumption determines that a change in the formulation of the formula or a change in the processing of the formula may affect whether the formula is adulterated under subsection (a) of this section, the manufacturer shall, before the first processing of such formula, make the submission to the Secretary required by paragraph (1).

**(e) Additional notice requirements for manufacturer**

(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—

(A) may not provide the nutrients required by subsection (i) of this section, or

(B) may be otherwise adulterated or misbranded,

the manufacturer shall promptly notify the Secretary of such knowledge. If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

(2) For purposes of paragraph (1), the term ''knowledge'' as applied to a manufacturer means (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

**(f) Procedures applicable to recalls by manufacturer; regulatory oversight**

(1) If a recall of infant formula is begun by a manufacturer, the recall shall be carried out in accordance with such requirements as the Secretary shall prescribe under paragraph (2) and—

(A) the Secretary shall, not later than the 15th day after the beginning of such recall and at least once every 15 days thereafter until the recall is terminated, review the actions taken under the recall to determine whether the recall meets the requirements prescribed under paragraph (2), and

(B) the manufacturer shall, not later than the 14th day after the beginning of such recall and at least once every 14 days thereafter until the recall is terminated, report to the Secretary the actions taken to implement the recall.

(2) The Secretary shall by regulation prescribe the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risks to human health presented by the formula subject to the recall.

(3) The Secretary shall by regulation require each manufacturer of an infant formula who begins a recall of such formula because of a risk to human health to request each retail establishment at which such formula is sold or available for sale to post at the point of purchase of such formula a notice of such recall at such establishment for such time that the Secretary determines necessary to inform the public of such recall.

**(g) Recordkeeping requirements for manufacturer; regulatory oversight and enforcement**

(1) Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula.

(2) To the extent that the Secretary determines that records are not being made or maintained in accordance with paragraph (1), the Secretary may by regulation prescribe the records required to be made under paragraph (1) and requirements respecting the retention of such records under such paragraph. Such regulations shall take effect on such date as the Secretary prescribes but not sooner than the 180th day after the date such regulations are promulgated. Such regulations shall apply only with respect to distributions of infant formulas made after such effective date.

**(h) Exemptions; regulatory oversight**

(1) Any infant formula which is represented and labeled for use by an infant—

(A) who has an inborn error of metabolism or a low birth weight, or

(B) who otherwise has an unusual medical or dietary problem,

is exempt from the requirements of subsections (a), (b), and (c) of this section. The manufacturer of an infant formula exempt under this paragraph shall, in the case of the exempt formula, be required to provide the notice required by subsection (e)(1) of this section only with respect to adulteration or misbranding described in subsection (e)(1)(B) of this section and to comply with the regulations prescribed by the Secretary under paragraph (2).

(2) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a), (b), and (c) of this section. An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if such formula is not in compliance with applicable terms and conditions prescribed under this paragraph.

**(i) Nutrient requirements**

(1) An infant formula shall contain nutrients in accordance with the table set out in this subsection or, if revised by the Secretary under paragraph (2), as so revised.

(2) The Secretary may by regulation—

(A) revise the list of nutrients in the table in this subsection, and

(B) revise the required level for any nutrient required by the table.

NUTRIENTS

| Nutrient | Minimum[a] | | Maximum[a] |
|---|---|---|---|
| Protein (gm) | 1.8[b] | | 4.5. |
| Fat: | | | |
| gm | 3.3 | | 6.0. |
| percent cal | 30.0 | | 54.0. |
| Essential fatty acids (linoeate): | | | |
| percent cal | 2.7 | | |
| mg | 300.0 | | |
| Vitamins: | | | |
| A (IU) | 250.0 | (75 μg)[c] | 750.0 (225 μg).[c] |
| D (IU) | 40.0 | | 100.0. |
| K (μg) | 4.0 | | |
| E (IU) | 0.7 | (with 0.7 IU/gm linoleic acid). | |
| C (ascorbic acid) (mg) | 8.0 | | |
| $B_1$ (thiamine) (μg) | 40.0 | | |
| $B_2$ (riboflavin) (μg) | 60.0 | | |
| $B_6$ (pyridoxine) (μg) | 35.0 | (with 15 μg/gm of protein in formula). | |
| $B_{12}$ (μg) | 0.15 | | |
| Niacin (μg) | 250.0 | | |
| Folic acid (μg) | 4.0 | | |
| Pantothenic acid (μg) | 300.0 | | |
| Biotin (μg) | 1.5[d] | | |
| Choline (mg) | 7.0[d] | | |
| Inositol (mg) | 4.0[d] | | |
| Minerals: | | | |
| Calcium (mg) | 50.0[e] | | |
| Phosphorus (mg) | 25.0[e] | | |
| Magnesium (mg) | 6.0 | | |
| Iron (mg) | 0.15 | | |
| Iodine (μg) | 5.0 | | |
| Zinc (mg) | 0.5 | | |
| Copper (μg) | 60.0 | | |
| Manganese (μg) | 5.0 | | |
| Sodium (mg) | 20.0 | | 60.0. |
| Potassium (mg) | 80.0 | | 200.0. |
| Chloride (mg) | 55.0 | | 150.0. |

[a] Stated per 100 kilocalories.
[b] The source of protein shall be at least nutritionally equivalent to casein.
[c] Retinol equivalents.
[d] Required to be included in this amount only in formulas which are not milk-based.

[e] Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.

(June 25, 1938, ch. 675, § 412, as added Sept. 26, 1980, Pub. L. 96–359, § 2, 94 Stat. 1190; amended Oct. 27, 1986, Pub. L. 99–570, title IV, § 4014(a), (b)(1), 100 Stat. 3207–116, 3207–120; Aug. 13, 1993, Pub. L. 103–80, § 3(*l*), 107 Stat. 777.)

AMENDMENTS

1993—Subsec. (h)(1). Pub. L. 103–80 substituted ''(e)(1)(B) of this section'' for ''(c)(1)(B) of this section,'' in concluding provisions.

1986—Subsecs. (a) to (d). Pub. L. 99–570, § 4014(a)(7), added subsecs. (a) to (d) and struck out former subsecs. (a) relating to adulteration and regulatory oversight, (b) relating to notice to the Secretary by a manufacturer and requirements and scope of that notice, (c) relating to additional notice requirements for the manufacturer, and (d) relating to procedures applicable to recalls by a manufacturer.

Subsecs. (e), (f). Pub. L. 99–570, § 4014(a)(1), (7), added subsecs. (e) and (f) and redesignated former subsecs. (e) and (f) as (g) and (h), respectively.

Subsec. (g). Pub. L. 99–570, § 4014(a)(1), (2), redesignated subsec. (e) as (g) and substituted ''Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula'' for ''No manufacturer shall be required under this subsection to retain any record respecting the distribution of an infant formula for a period of longer than 2 years from the date the record was made''. Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 99–570, § 4014(a)(1), redesignated subsec. (f) as (h).

Subsec. (h)(1). Pub. L. 99–570, § 4014(a)(3), (4), substituted ''(a), (b), and (c)'' for ''(a) and (b)'' and ''(e)(1)'' for ''(c)(1)''.

Pub. L. 99–570, § 4014(a)(5), which directed that ''(d)(1)(B)'' be substituted for ''(e)(1)(B)'' in second sentence could not be executed because ''(e)(1)(B)'' did not appear. See 1993 Amendment note above.

Subsec. (h)(2). Pub. L. 99–570, § 4014(a)(6), substituted ''(a), (b), and (c)'' for ''(a) and (b)''.

Subsec. (i). Pub. L. 99–570, § 4014(a)(1), (b)(1), redesignated subsec. (g) as (i), designated existing provisions as par. (1), substituted ''paragraph (2)'' for ''subsection (a)(2) of this section'', substituted a period for the colon after ''as so revised'', and added par. (2).

EFFECTIVE DATE OF 1980 AMENDMENT

Section 6 of Pub. L. 96–359 provided that: ''Section 412 of the Federal Food, Drug, and Cosmetic Act (added by section 2) [this section] shall apply with respect to infant formulas manufactured on or after the 90th day after the date of the enactment of this Act [Sept. 26, 1980].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 343, 374 of this title.

### § 350b. New dietary ingredients

#### (a) In general

A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 342(f) of this title unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

#### (b) Petition

Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, the decision of the Secretary shall be considered final agency action.

#### (c) "New dietary ingredient" defined

For purposes of this section, the term ''new dietary ingredient'' means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.

(June 25, 1938, ch. 675, § 413, as added Oct. 25, 1994, Pub. L. 103–417, § 8, 108 Stat. 4331.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 331 of this title.

## SUBCHAPTER V—DRUGS AND DEVICES

### PART A—DRUGS AND DEVICES

### § 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

#### (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or

is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 379e(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title.

**(b) Strength, quality, or purity differing from official compendium**

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

**(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium**

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

**(d) Mixture with or substitution of another substance**

If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

**(e) Devices not in conformity with performance standards**

If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 360d of this title unless such device is in all respects in conformity with such standard.

**(f) Certain class III devices**

(1) If it is a class III device—

(A)(i) which is required by a regulation promulgated under subsection (b) of section 360e of this title to have an approval under such section of an application for premarket approval and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 360c(f) of this title into class III, which under section 360e(a) of this title is required to have in effect an approved application for premarket approval, and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 360j(*l*) of this title into class III, which under such section is required to have in effect an approved application under section 360e of this title, and which has an application which has been suspended or is otherwise not in effect.

(2)(A) In the case of a device classified under section 360c(f) of this title into class III and intended solely for investigational use, paragraph[1] (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 360j(g)(2) of this title.

(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 360e of this title, paragraph[1] (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 360c of this title, or

(ii) on the ninetieth day after the date of the promulgation of such regulation,

whichever occurs later.

**(g) Banned devices**

If it is a banned device.

[1] So in original. Probably should be "subparagraph".

**(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions**

If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 360j(f)(1) of this title or an applicable condition prescribed by an order under section 360j(f)(2) of this title.

**(i) Failure to comply with requirements under which device was exempted for investigational use**

If it is a device for which an exemption has been granted under section 360j(g) of this title for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

(June 25, 1938, ch. 675, § 501, 52 Stat. 1049; July 12, 1960, Pub. L. 86–618, title I, § 102(b)(1), 74 Stat. 398; Oct. 10, 1962, Pub. L. 87–781, title I, § 101, 76 Stat. 780; July 13, 1968, Pub. L. 90–399, § 101(a), 82 Stat. 343; May 28, 1976, Pub. L. 94–295, §§ 3(d), 9(b)(1), 90 Stat. 576, 583; Nov. 28, 1990, Pub. L. 101–629, § 9(b), 104 Stat. 4521; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(8), 106 Stat. 4499.)

AMENDMENTS

1992—Par. (a)(4). Pub. L. 102–571 substituted ''379e(a)'' for ''376(a)'' in cls. (A) and (B).

1990—Par. (f)(1). Pub. L. 101–629, § 9(b), which directed the amendment of subpars. (A) to (C) of par. (f), was executed by making the amendments in cls. (A) to (C) of subpar. (1) of par. (f) as follows to reflect the probable intent of Congress: in cl. (A)(ii)(II), substituted '', suspended, or withdrawn'' for ''or withdrawn''; in cl. (B)(ii), substituted ''which has an application which has been suspended or is otherwise not in effect'' for ''which does not have such an application in effect''; and in cl. (C), substituted ''which has an application which has been suspended or is otherwise not in effect'' for ''which does not have such an application in effect''.

1976—Par. (a). Pub. L. 94–295, § 9(b)(1), substituted ''(3) if its'' for ''(3) if it is a drug and its'' in cl. (3), substituted ''(4) if (A) it bears or contains'' for ''(4) if (A) it is a drug which bears or contains'' in cl. (4)(A), and substituted ''drugs or devices'' for ''drugs'' in cl. (4)(B).

Pars. (e) to (i). Pub. L. 94–295, § 3(d), added pars. (e) to (i).

1968—Par. (a). Pub. L. 90–399 added cls. (5) and (6).

1962—Par. (a). Pub. L. 87–781 designated existing provisions of cl. (2) as (A) and added (B).

1960—Par. (a). Pub. L. 86–618 substituted provisions in cl. (4) relating to unsafe color additives for provisions which related to a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 354 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87–781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE; POSTPONEMENT

Par. (a)(4) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 333, 334, 356, 357, 360b, 360c, 360j, 371, 379e, 382 of this title.

## § 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

**(a) False or misleading label**

If its labeling is false or misleading in any particular.

**(b) Package form; contents of label**

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

**(c) Prominence of information on label**

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

**(d) Habit forming substances**

If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement ''Warning—May be habit forming.''

**(e) Designation of drugs or devices by established names**

(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the estab-

lished name (as defined in subparagraph (3)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury ouabain strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term ''established name'', with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 358 of this title, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply.

(4) As used in subparagraph (2), the term ''established name'' with respect to a device means (A) the applicable official name of the device designated pursuant to section 358 of this title, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

**(f) Directions for use and warnings on label**

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

**(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug**

If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

**(h) Deteriorative drugs; packing and labeling**

If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

**(i) Drug; misleading container; imitation; offer for sale under another name**

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

**(j) Health-endangering when used as prescribed**

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

**(k) Insulin not properly certified**

If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which

a certificate or release has been issued pursuant to section 356 of this title, and (2) such certificate or release is in effect with respect to such drug.

**(*l*) Antibiotic drugs improperly certified**

If it is, or purports to be, or is represented as a drug (except a drug for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357(c) or (d) of this title.

**(m) Color additives; packing and labeling**

If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 379e of this title.

**(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances**

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragraph (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of title 15. This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers.

**(*o*) Drugs or devices from nonregistered establishments**

If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 360 of this title, if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires.

**(p) Packaging or labeling of drugs in violation of regulations**

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

**(q) Restricted devices using false or misleading advertising or used in violation of regulations**

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

**(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter**

In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of title 15. This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

**(s) Devices subject to performance standards not bearing requisite labeling**

If it is a device subject to a performance standard established under section 360d of this

title, unless it bears such labeling as may be prescribed in such performance standard.

**(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information**

If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 360h of this title respecting the device, (2) to furnish any material or information required by or under section 360i of this title respecting the device, or (3) to comply with a requirement under section 360*l* of this title.

(June 25, 1938, ch. 675, § 502, 52 Stat. 1050; June 23, 1939, ch. 242, § 3, 53 Stat. 854; Dec. 22, 1941, ch. 613, § 2, 55 Stat. 851; July 6, 1945, ch. 281, § 2, 59 Stat. 463; Mar. 10, 1947, ch. 16, § 2, 61 Stat. 11; July 13, 1949, ch. 305, § 1, 63 Stat. 409; Aug. 5, 1953, ch. 334, § 1, 67 Stat. 389; July 12, 1960, Pub. L. 86–618, title I, § 102(b)(2), 74 Stat. 398; Oct. 10, 1962, Pub. L. 87–781, title I, §§ 105(c), 112(a), (b), 131(a), title III, § 305, 76 Stat. 785, 790, 791, 795; July 13, 1968, Pub. L. 90–399, § 105(a), 82 Stat. 352; Dec. 30, 1970, Pub. L. 91–601, § 6(d), formerly § 7(d), 84 Stat. 1673, renumbered Aug. 13, 1981, Pub. L. 97–35, title XII, § 1205(c), 95 Stat. 716; May 28, 1976, Pub. L. 94–295, §§ 3(e), 4(b)(2), 5(a), 9(b)(2), 90 Stat. 577, 580, 583; Nov. 10, 1978, Pub. L. 95–633, title I, § 111, 92 Stat. 3773; June 16, 1992, Pub. L. 102–300, § 3(a)(2), 106 Stat. 239; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(9), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103–80, § 3(m), 107 Stat. 777.)

AMENDMENTS

1993—Par. (e)(3). Pub. L. 103–80, § 3(m)(1), substituted ''of such ingredient, except that'' for ''of such ingredient: *Provided*, That''.

Par. (f). Pub. L. 103–80, § 3(m)(2), substituted ''users, except that where'' for ''users: *Provided*, That where''.

Par. (g). Pub. L. 103–80, § 3(m)(3), substituted ''prescribed therein. The method'' for ''prescribed therein: *Provided*, That the method'' and ''Pharmacopoeia, except that'' for ''Pharmacopoeia: *Provided further*, That,''.

Par. (n). Pub. L. 103–80, § 3(m)(4), substituted '', except that (A)'' for '': *Provided*, That (A)''.

1992—Par. (m). Pub. L. 102–571 substituted ''379e'' for ''376''.

Par. (t)(3). Pub. L. 102–300 added cl. (3).

1978—Par. (n). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1976—Par. (e). Pub. L. 94–295, § 5(a), substituted ''subparagraph (3)'' for ''subparagraph (2)'' in subpar. (1), added subpar. (2), redesignated former subpar. (2) as (3) and in subpar. (3) as so redesignated substituted ''subparagraph (1)'' for ''this paragraph (e)'', and added subpar. (4).

Par. (j). Pub. L. 94–295, § 3(e)(2), substituted ''dosage or manner,'' for ''dosage,''.

Par. (m). Pub. L. 94–295, § 9(b)(2), substituted ''the intended use of which is for'' for ''the intended use of which in or on drugs is for''.

Par. (*o*). Pub. L. 94–295, § 4(b)(2), substituted ''If it was manufactured'' for ''If it is a drug and was manufactured'' and inserted '', if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires''.

Pars. (q) to (t). Pub. L. 94–295, § 3(e)(1), added pars. (q) to (t).

1970—Par. (p). Pub. L. 91–601 added par. (p).

1968—Par. (*l*). Pub. L. 90–399 inserted ''(except a drug for use in animals other than man)'' after ''represented as a drug''.

1962—Par. (e). Pub. L. 87–781, § 112(a), designated existing provisions as subpar. (1), substituted '', unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2) of this subsection) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity'' for ''and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name'', and ''the established name'' for ''the name'', provided that the requirement for stating the quantity of active ingredients, other than those specified in this par., applies only to prescription drugs, and that the established name of a drug on a label is to be printed prominently and in type at least half as large as used for any proprietary designation, and added subpar. (2) defining ''established name''.

Par. (g). Pub. L. 87–781, § 112(b), provided that if there is an inconsistency between the provisions of this par. and those of par. (e), as to the name of a drug, the requirements of par. (e) should prevail.

Par. (*l*). Pub. L. 87–781, § 105(c), substituted ''bacitracin, or any other antibiotic drug'' for ''or bacitracin.''

Par. (n). Pub. L. 87–781, § 131(a), added par. (n).

Par. (*o*). Pub. L. 87–781, § 305, added par. (*o*).

1960—Par. (m). Pub. L. 86–618 added par. (m).

1953—Par. (*l*). Act Aug. 5, 1953, substituted ''chlortetracycline'' for ''aureomycin''.

1949—Par. (*l*). Act July 13, 1949, inserted '', aureomycin, chloramphenicol, or bacitracin'' after ''streptomycin''.

1947—Par. (*l*). Act Mar. 10, 1947, inserted ''or streptomycin'' after ''penicillin''.

1945—Par. (*l*). Act July 6, 1945, added par. (*l*).

1941—Par. (k). Act Dec. 22, 1941, added par. (k).

1939—Par. (d). Act June 29, 1939, substituted ''name, and quality or proportion'' for ''name, quantity, and percentage''.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Section 112(c) of Pub. L. 87–781 provided that: ''This section [amending this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [October 1962].''

Section 131(b) of Pub. L. 87–781 provided that: ''No drug which was being commercially distributed prior to the date of enactment of this Act [Oct. 10, 1962] shall be

deemed to be misbranded under paragraph (n) of section 502 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(n)], as added by this section, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; or (2) the effective date of regulations first issued under clause (3) of such paragraph (n) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(e)].''

Amendment by Pub. L. 87–781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE; POSTPONEMENT

Pars. (b) and (d) to (h) effective Jan. 1, 1940, and such paragraphs effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date: Postponement in Certain Cases note under section 301 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

COUNTERFEITING OF DRUGS; CONGRESSIONAL FINDINGS AND DECLARATION OF POLICY

Section 9(a) of Pub. L. 89–74, July 15, 1965, 79 Stat. 234, provided that: ''The Congress finds and declares that there is a substantial traffic in counterfeit drugs simulating the brand or other identifying mark or device of the manufacturer of the genuine article; that such traffic poses a serious hazard to the health of innocent consumers of such drugs because of the lack of proper qualifications, facilities, and manufacturing controls on the part of the counterfeiter, whose operations are clandestine; that, while such drugs are deemed misbranded within the meaning of section 502(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352(i)], the controls for the suppression of the traffic in such drugs are inadequate because of the difficulty of determining the place of interstate origin of such drugs and, if that place is discovered, the fact that the implements for counterfeiting are not subject to seizure, and that these factors require enactment of additional controls with respect to such drugs without regard to their interstate or intrastate origins.''

Provisions as effective Feb. 1, 1966, see section 11 of Pub. L. 89–74, set out as an Effective Date of 1965 Amendment note under section 321 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 353, 357, 360, 360b, 360c, 360j, 371, 802 of this title; title 42 section 1396r–8.

## § 353. Exemptions and consideration for certain drugs, devices, and biological products

### (a) Regulations for goods to be processed, labeled, or repacked elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

### (b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (*l*), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement ''Caution: Federal law prohibits dispensing without prescription''. A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its

label bears the caution statement quoted in the preceding sentence.

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of title 26, or to marihuana as defined in section 4761 of title 26.

**(c) Sales restrictions**

(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d) of this section, the term ''drug sample'' means a unit of a drug, subject to subsection (b) of this section, which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term ''coupon'' means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b) of this section.

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b) of this section, and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of title 26.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b) of this section.

For purposes of this paragraph, the term ''entity'' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term ''emergency medical reasons'' includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

**(d) Distribution of drug samples**

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term ''distribute'' does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of

record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) of this section or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

**(e) Wholesale distributors; guidelines for licensing; definitions**

(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) of this section and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

(B) Each manufacturer of a drug subject to subsection (b) of this section shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) of this section in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b) of this section. Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

(3) For the purposes of this subsection and subsection (d) of this section—

(A) the term ''authorized distributors of record'' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term ''wholesale distribution'' means distribution of drugs subject to subsection (b) of this section to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B) of this section.

**(f) Veterinary prescription drugs**

(1)(A) A drug intended for use by animals other than man which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 360b of this title to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order

promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) shall be exempt from the requirements of section 352 of this title, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 360b of this title from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''. A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

**(g) Regulation of combination products**

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after November 28, 1990.

(4) As used in this subsection:

(A) The term ''biological product'' has the meaning given the term in section 262(a) of title 42.

(B) The term ''market clearance'' includes—

(i) approval of an application under section 355, 357, 360e, or 360j(g) of this title,

(ii) a finding of substantial equivalence under this part, and

(iii) approval of a product or establishment license under subsection (a) or (d) of section 262 of title 42.

(June 25, 1938, ch. 675, § 503, 52 Stat. 1051; Oct. 26, 1951, ch. 578, § 1, 65 Stat. 648; Oct. 10, 1962, Pub. L. 87–781, title I, § 104(e)(2), 76 Stat. 785; Dec. 30, 1970, Pub. L. 91–601, § 6(e), formerly § 7(e), 84 Stat. 1673, renumbered Aug. 13, 1981, Pub. L. 97–35, title XII, § 1205(c), 95 Stat. 716; Apr. 22, 1988, Pub. L. 100–293, §§ 4–6, 102 Stat. 96–98; Nov. 16, 1988, Pub. L. 100–670, title I, § 105, 102 Stat. 3983; Nov. 28, 1990, Pub. L. 101–629, § 16(a), 104 Stat. 4526; Aug. 17, 1991, Pub. L. 102–108, § 2(d), 105 Stat. 550; June 16, 1992, Pub. L. 102–300, § 6(d), 106 Stat. 240; Aug. 26, 1992, Pub. L. 102–353, §§ 2(a)–(c), 4, 106 Stat. 941, 942.)

CODIFICATION

In subsec. (b)(5), ''sections 4721, 6001, and 6151 of title 26'' and ''section 4761 of title 26'' substituted for ''section 3220 of the Internal Revenue Code (26 U.S.C. 3220)'' and ''section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b))'', respectively, on authority of section 7852(b) of Title 26, Internal Revenue Code.

AMENDMENTS

1992—Subsec. (d)(1). Pub. L. 102–353, § 4(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''Except as provided in paragraphs (2) and (3), no representative of a drug manufacturer or distributor may distribute any drug sample.''

Subsec. (d)(2). Pub. L. 102–353, § 4(2), substituted ''authorized distributor of record'' for ''distributor'' wherever appearing.

Subsec. (d)(3). Pub. L. 102–353, § 4(2), substituted ''authorized distributor of record'' for ''distributor'' and ''authorized distributors of record'' for ''distributors'' wherever appearing.

Subsec. (e)(1). Pub. L. 102–353, § 4(3), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''Each person who is engaged in the wholesale distribution of drugs subject to subsection (b) of this section and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of the sale) before the sale to such wholesale distributor. Each manufacturer shall maintain at its corporate offices a current list of such authorized distributors.''

Subsec. (e)(2)(A). Pub. L. 102–353, § 2(a), (d), temporarily inserted ''or has registered with the Secretary in accordance with paragraph (3)''. See Termination Date of 1992 Amendment note below.

Subsec. (e)(3). Pub. L. 102–353, § 2(b), (d), temporarily added par. (3). Former par. (3) redesignated (4). See Termination Date of 1992 Amendment note below.

Subsec. (e)(4). Pub. L. 102–353, § 4(4), inserted ''and subsection (d) of this section'' after ''For the purposes of this subsection''.

Pub. L. 102–353, § 2(b), (d), temporarily redesignated par. (3) as (4). See Termination Date of 1992 Amendment note below.

Subsec. (f)(1)(B). Pub. L. 102–353, §2(c), which directed the substitution of ''an order'' for ''and order'', could not be executed because ''and order'' did not appear in subpar. (B).

Subsec. (g)(3). Pub. L. 102–300 substituted ''clearance'' for ''approval''.

1991—Subsec. (c). Pub. L. 102–108, §2(d)(3), redesignated subsec. (c), relating to veterinary prescription drugs, as (f). Former subsec. (f) redesignated (g).

Subsec. (c)(2), (3)(B)(v). Pub. L. 102–108, §2(d)(1), made technical amendment to reference to subsection (b) of this section involving corresponding provision of original act.

Subsec. (d)(3)(E). Pub. L. 102–108, §2(d)(2), made technical amendment to reference to subsection (c)(1) of this section involving corresponding provision of original act.

Subsec. (f). Pub. L. 102–108, §2(d)(4), redesignated subsec. (f), relating to regulation of combination products, as (g).

Pub. L. 102–108, §2(d)(3), redesignated subsec. (c), relating to veterinary prescription drugs, as (f).

Subsec. (g). Pub. L. 102–108, §2(d)(4), redesignated subsec. (f), relating to regulation of combination products, as (g).

1990—Pub. L. 101–629, §16(a)(1), substituted ''Exemptions and consideration for certain drugs, devices, and biological products'' for ''Exemptions in case of drugs and devices'' in section catchline.

Subsec. (f). Pub. L. 101–629, §16(a)(2), added subsec. (f).

1988—Subsec. (c). Pub. L. 100–670 added subsec. (c) relating to veterinary prescription drugs.

Pub. L. 100–293, §4, added subsec. (c) relating to sales restrictions.

Subsec. (d). Pub. L. 100–293, §5, added subsec. (d).

Subsec. (e). Pub. L. 100–293, §6, added subsec. (e).

1970—Subsec. (b)(2). Pub. L. 91–601 included exemption from packaging requirements of subsec. (p) of section 352 of this title.

1962—Subsec. (b)(1)(C). Pub. L. 87–781 substituted ''approved'' for ''effective''.

1951—Subsec. (b). Act Oct. 26, 1951, amended subsec. (b) generally to protect the public from abuses in the sale of potent prescription drugs, and to relieve retail pharmacists and the public from unnecessary restrictions on the dispensation of drugs that are safe to use without supervision of a doctor.

TERMINATION DATE OF 1992 AMENDMENT

Section 2(d) of Pub. L. 102–353 provided that: ''Effective September 14, 1994, the amendments made by subsections (a) and (b) [amending this section] shall no longer be in effect.''

EFFECTIVE DATE OF 1988 AMENDMENT

Section 8 of Pub. L. 100–293 provided that:

''(a) GENERAL RULE.—Except as provided in subsection (b), this Act and the amendments made by this Act [amending this section and sections 331, 333, and 381 of this title and enacting provisions set out as notes under this section and section 301 of this title] shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Apr. 22, 1988].

''(b) EXCEPTION.—

''(1) Section 503(d) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(d)] (as added by section 5 of this Act) shall take effect upon the expiration of 180 days after the date of the enactment of this Act [Apr. 22, 1988].

''(2) The Secretary of Health and Human Services shall by regulation issue the guidelines required by section 503(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(e)(2)(B)] (as added by section 6 of this Act) not later than 180 days after the date of the enactment of this Act. Section 503(e)(2)(A) of such Act shall take effect upon the expiration of 2 years after the date such regulations are promulgated and take effect.''

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1951 AMENDMENT

Amendment by act Oct. 26, 1951, effective six months after Oct. 26, 1951, see section 3 of act Oct. 26, 1951, set out as a note under section 333 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

CONGRESSIONAL FINDINGS

Section 2 of Pub. L. 100–293 provided that: ''The Congress finds the following:

''(1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.

''(2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.

''(3) The existence and operation of a wholesale submarket, commonly known as the 'diversion market', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

''(4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.

''(5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

''(6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

''(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

''(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 360, 379g, 381, 825, 829, 885 of this title; title 15 section 1459; title 35 section 156.

## §354. Repealed. Pub. L. 86–618, title I, §103(a)(2), July 12, 1960, 74 Stat. 398

Section, act June 25, 1938, ch. 675, §504, 52 Stat. 1052, directed Secretary to promulgate regulations for listing of coal-tar colors. See section 379e of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L.

86–618, set out as an Effective Date of 1960 Amendment note under section 379e of this title.

## § 355. New drugs

### (a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

### (b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.

### (c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A) of this section, the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,

(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of title 28 for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) of this section before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under subsection (b) of this section after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A) of this section. The approval of such an application shall be made effective in accordance with this paragraph except that,

if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty[1] studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

**(d) Grounds for refusing application; approval of application; "substantial evidence" defined**

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term ''substantial evidence'' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

**(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health**

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw

[1] So in original. Probably should be ''bioavailability''.

approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

**(f) Revocation of order refusing, withdrawing or suspending approval of application**

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

**(g) Service of orders**

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

**(h) Appeal from order**

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals or the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the

Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

**(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary**

The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section.

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

**(j) Abbreviated new drug applications**

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a ''listed drug'');

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph

(2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the appli-

cant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(6)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has

been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (5), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(7) For purposes of this subsection:

(A) The term ''bioavailability'' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(8) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

**(k) Records and reports; required information; regulations and orders; access to records**

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

**(*l*) Public disclosure of safety and effectiveness data**

Safety and effectiveness data and information which has been submitted in an application under subsection (b) of this section for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) of this section is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) of this section which refers to such drug or upon

the date upon which the approval of an application under subsection (j) of this section which refers to such drug could be made effective if such an application had been submitted.

**(m) "Patent" defined**

For purposes of this section, the term ''patent'' means a patent issued by the Patent and Trademark Office of the Department of Commerce.

(June 25, 1938, ch. 675, §505, 52 Stat. 1052; June 11, 1960, Pub. L. 86–507, §1(18), 74 Stat. 201; Oct. 10, 1962, Pub. L. 87–781, title I, §§102(b)–(d), 103(a), (b), 104(a)–(d)(2), 76 Stat. 781–783, 784, 785; Aug. 16, 1972, Pub. L. 92–387, §4(d), 86 Stat. 562; Sept. 24, 1984, Pub. L. 98–417, title I, §§101, 102(a)–(b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub. L. 102–282, §5, 106 Stat. 161; Aug. 13, 1993, Pub. L. 103–80, §3(n), 107 Stat. 777.)

AMENDMENTS

1993—Subsec. (j)(6)(A)(ii). Pub. L. 103–80, §3(n)(1)(A), substituted ''Secretary'' for ''Secretry''.

Subsec. (j)(6)(A)(iii). Pub. L. 103–80, §3(n)(1)(B), inserted comma after ''published by the Secretary''.

Subsec. (k)(1). Pub. L. 103–80, §3(n)(2), substituted ''section. Regulations'' for ''section: *Provided, however*, That regulations''.

1992—Subsec. (j)(8). Pub. L. 102–282 added par. (8).

1984—Subsec. (a). Pub. L. 98–417, §102(b)(1), inserted ''or (j)'' after ''subsection (b)''.

Subsec. (b). Pub. L. 98–417, §§102(a)(1), 103(a), designated existing provisions of subsec. (b) as par. (1) thereof and redesignated existing cls. (1) through (6) of such par. (1) as cls. (A) through (F) thereof, respectively, inserted requirement that the applicant file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably by asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, that the applicant amend the application to include such information if an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, and that upon approval of the application, the Secretary publish the information submitted, and added pars. (2) and (3).

Subsec. (c). Pub. L. 98–417, §§102(a)(2), (b)(2), 103(b), designated existing provisions of subsec. (c) as par. (1) thereof and in par. (1) as so designated substituted ''subsection (b) of this section'' for ''this subsection'' and redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, and added pars. (2) and (3).

Subsec. (d)(6), (7). Pub. L. 98–417, §102(a)(3)(A), added cl. (6) relating to the failure of the application to contain the patent information prescribed by subsec. (b) of this section, and redesignated former cl. (6) as (7).

Subsec. (e). Pub. L. 98–417, §102(a)(3)(B), in first sentence, added a new cl. (4) relating to the failure to file the patent information prescribed by subsec. (c) of this section within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information, and redesignated former cl. (4) as (5).

Pub. L. 98–417, §102(b)(3), (4), in second sentence, inserted in provisions preceding cl. (1) ''submitted under subsection (b) or (j) of this section'' and in cl. (1) substituted ''under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title'' for ''under subsection (j) of this section or to comply with the notice requirements of section 360(j)(2) of this title''.

Subsecs. (j), (k). Pub. L. 98–417, §101, added subsec. (j) and redesignated former subsec. (j) as (k).

Subsec. (k)(1). Pub. L. 98–417, §102(b)(5), substituted ''under subsection (b) or (j) of this section'' for ''pursuant to this section''.

Subsecs. (*l*), (m). Pub. L. 98–417, §104, added subsecs. (*l*) and (m).

1972—Subsec. (e). Pub. L. 92–387 inserted ''or to comply with the notice requirements of section 360(j)(2) of this title'' in cl. (1) of second sentence relating to the maintenance of records.

1962—Subsec. (a). Pub. L. 87–781, §104(a), inserted ''an approval of'' before ''an application''.

Subsec. (b). Pub. L. 87–781, §102(b), inserted ''and whether such drug is effective in use'' after ''is safe for use''.

Subsec. (c). Pub. L. 87–781, §104(b), substituted provisions requiring the Secretary, within 180 days after filing an application, or such additional period as the Secretary and the applicant agree upon, to either approve the application, if meeting the requirements of subsec. (d) of this section, or give notice of opportunity for hearing on question of whether such application is approvable, and providing that if applicant requests hearing in writing within 30 days, the hearing shall begin within 90 days after expiration of said 30 days, unless the Secretary and applicant agree otherwise, that such hearing shall be expedited, and that the Secretary's order shall be issued within 90 days after date for filing final briefs, for provisions which had an application become effective on the sixtieth day after filing thereof unless prior thereto the Secretary postponed the date by written notice to such time, but not more than 180 days after filing, as the Secretary deemed necessary to study and investigate the application.

Subsec. (d). Pub. L. 87–781, §102(c), inserted references to subsec. (c), added cls. (5) and (6), provided that if after notice and opportunity for hearing, the Secretary finds that cls. (1) to (6) do not apply, he shall approve the application, and defined ''substantial evidence'' as used in this subsection and subsec. (e) of this section.

Subsec. (e). Pub. L. 87–781, §102(d), amended subsec. (e) generally, and among other changes, directed the Secretary to withdraw approval of an application if by tests, other scientific data or experience, or new evidence of clinical experience not contained in the application or available at the time of its approval, the drug is shown to be unsafe, or on the basis of new information, there is shown a lack of substantial evidence that the drug has the effect it is represented to have, and provided that if the Secretary, or acting Secretary, finds there is an imminent hazard to the public health, he may suspend approval immediately, notify the applicant, and give him opportunity for an expedited hearing, that the Secretary may withdraw approval if the applicant fails to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain records and make reports, or has refused access to, or copying or verification of such records, or if the Secretary finds on new evidence that the methods, facilities and controls in the manufacturing, processing, and packing are inadequate to assure and preserve the drugs' identity, strength, quality and purity, and were not made adequate within a reasonable time after receipt of written notice thereof, or finds on new evidence, that the labeling is false or misleading and was not corrected within a reasonable time after receipt of written notice thereof.

Subsec. (f). Pub. L. 87–781, §104(c), substituted provisions requiring the Secretary to revoke any previous order under subsecs. (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and to approve such application or reinstate such approval, for provisions which required him to revoke an order refusing effectiveness to an application.

Subsec. (h). Pub. L. 87–781, §104(d)(1), (2), inserted ''as provided in section 2112 of title 28'', and ''except that until the filing of the record the Secretary may modify or set aside his order'', substituted ''or withdrawing approval of an application under this section'' for ''to permit the application to become effective, or suspending the effectiveness of the application'', ''United States court of appeals for the circuit'' for ''district court of the United States within any district'', ''Court of Appeals for the District of Columbia Circuit'' for ''District

Court for the District of Columbia'', ''transmitted by the clerk of the court to'' for ''served upon'', and ''by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28'' for ''as provided in sections 225, 346, and 347 of title 28, as amended, and in section 7, as amended, of the Act entitled 'An Act to establish a Court of Appeals for the District of Columbia', approved February 9, 1893'', and eliminated ''upon'' before ''any officer designated'', ''a transcript of'' before ''the record'' and ''and decree'' before ''of the court affirming''.

Subsec. (i). Pub. L. 87–781, § 103(b), inserted ''the foregoing subsections of'' after ''operation of'', and ''and effectiveness'' after ''safety'', and provided that the regulations may condition exemptions upon the submission of reports of preclinical tests to justify the proposed clinical testing, upon the obtaining by the manufacturer or sponsor of the investigation of a new drug of a signed agreement from each of the investigators that patients to whom the drug is administered will be under his supervision or under investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings, or upon the establishment and maintenance of records and reports of data obtained by the investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug, and provided that the regulations shall condition an exemption upon the manufacturer or sponsor of the investigation requiring that experts using such drugs certify that they will inform humans to whom such drugs or any controls connected therewith are administered, or their representatives, and will obtain the consent of such people where feasible and not contrary to the best interests of such people, and that reports on the investigational use of drugs are not required to be submitted directly to the Secretary.

Subsec. (j). Pub. L. 87–781, § 103(a), added subsec. (j).

1960—Subsec. (g). Pub. L. 86–507 inserted ''or by certified mail'' after ''registered mail''.

EFFECTIVE DATE OF 1984 AMENDMENT

Section 105 of Pub. L. 98–417 provided that:

''(a) The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act [this section], as amended by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act [Sept. 24, 1984].

''(b) During the period beginning sixty days after the date of the enactment of this Act [Sept. 24, 1984], and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act [subsec. (c) of this section] before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act, except in accordance with such section.''

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–387 effective on first day of sixth month beginning after Aug. 16, 1972, see section 5 of Pub. L. 92–387, set out as a note under section 360 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 102–282

Amendment by Pub. L. 102–282 not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102–282, see section 7 of Pub. L. 102–282, set out as a note under section 335a of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

APPEALS TAKEN PRIOR TO OCTOBER 10, 1962

Section 104(d)(3) of Pub. L. 87–781 made amendments to subsec. (h) of this section inapplicable to any appeal taken prior to Oct. 10, 1962.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 333, 334, 335a, 353, 357, 360, 360b, 360j, 360aa to 360ee, 374, 379g, 379h, 381, 382, 802, 811, 827 of this title; title 16 section 4804; title 26 section 28; title 28 section 2201; title 35 sections 155A, 156, 271; title 42 sections 236, 300cc–12, 300cc–13, 300cc–17, 1395y, 1396r–8.

## § 356. Certification of drugs containing insulin

### (a) Standards for certification

The Secretary, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

### (b) Regulations

Regulations providing for such certification shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe no standard of identity or of strength, quality, or purity for any drug different from the standard of identity, strength, quality, or purity set forth for such drug in an official compendium.

**(c) Tests or methods of assay; revision**

Such regulations, insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, shall be prescribed, after notice and opportunity for revision of such compendium, in the manner provided in the second sentence of section 351(b) of this title. The provisions of subsections (e), (f), and (g) of section 371 of this title shall be applicable to such portion of any regulation as prescribes any such different test or method, but shall not be applicable to any other portion of any such regulation.

(June 25, 1938, ch. 675, § 506, as added Dec. 22, 1941, ch. 613, § 3, 55 Stat. 851; amended June 16, 1992, Pub. L. 102–300, § 6(b)(2), 106 Stat. 240; Aug. 13, 1993, Pub. L. 103–80, § 3(*o*), 107 Stat. 777.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–80 substituted ''Secretary'' for ''Federal Security Administrator'' in first sentence and for ''Administrator'' in two other places.

1992—Subsec. (a). Pub. L. 102–300, which directed the amendment of subsec. (a) by striking out ''of Health, Education, and Welfare'', could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions note below.

REGULATIONS

Section 4 of act Dec. 22, 1941, directed that regulations initially prescribed under this section were to be promulgated and made effective within forty-five days after Dec. 22, 1941.

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360 of this title; title 15 section 1459; title 38 section 8126; title 42 section 1396r–8.

## § 357. Certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug

**(a) Regulations prescribed by Secretary; release prior to certification; "antibiotic drug" defined**

The Secretary, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs (except drugs for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof. For purposes of this section and of section 352(*l*) of this title, the term ''antibiotic drug'' means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

**(b) Provisions of regulations**

Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section.

**(c) Exemption of drugs not involving safety and efficacy of use; considerations; certification after exemption; labeling and advertising claims**

Whenever in the judgment of the Administrator,[1] the requirements of this section and of section 352(*l*) of this title with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Administrator[1] shall promulgate regulations exempting such drug or class of drugs from such requirements. In deciding whether an antibiotic drug, or class of antibiotic drugs, is to be exempted from the requirement of certification the Secretary shall give consideration, among other relevant factors, to—

(1) whether such drug or class of drugs is manufactured by a person who has, or hereafter shall have, produced fifty consecutive batches of such drug or class of drugs in compliance with the regulations for the certification thereof within a period of not more than eighteen calendar months, upon the application by such person to the Secretary; or

(2) whether such drug or class of drugs is manufactured by any person who has otherwise demonstrated such consistency in the production of such drug or class of drugs, in compliance with the regulations for the certification thereof, as in the judgment of the

[1] See Transfer of Functions note below.

Secretary is adequate to insure the safety and efficacy of use thereof.

When an antibiotic drug or a drug manufacturer has been exempted from the requirement of certification, the manufacturer may still obtain certification of a batch or batches of that drug if he applies for and meets the requirements for certification. Nothing in this chapter shall be deemed to prevent a manufacturer or distributor of an antibiotic drug from making a truthful statement in labeling or advertising of the product as to whether it has been certified or exempted from the requirement of certification.

**(d) Exemption of drugs stored, processed, and labeled at plants other than manufacturer's, used in manufacture of other drugs or for investigational purposes; discretionary and mandatory conditions; direct reports to Secretary**

The Administrator[1] shall promulgate regulations exempting from any requirement of this section and of section 352(*l*) of this title, (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning the exemption under clause (3) of this subsection upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application for certification or release pursuant to subsection (a) of this section.

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

**(e) Exempted new drugs subject to section 355 of this title; request for certification of exempted drug; determination of compliance with sections 351(b) and 352(g) of this title**

No drug which is subject to this section shall be deemed to be subject to any provision of section 355 of this title except a new drug exempted from the requirements of this section and of section 352(*l*) of this title pursuant to regulations promulgated by the Secretary. For purposes of section 355 of this title, the initial request for certification, as thereafter duly amended, pursuant to this section, of a new drug so exempted shall be considered a part of the application filed pursuant to section 355(b) of this title with respect to the person filing such request and to such drug as of the date of the exemption. Compliance of any drug subject to section 352(*l*) of this title or this section with sections 351(b) and 352(g) of this title shall be determined by the application of the standards of strength, quality, and purity, the tests and methods of assay, and the requirements of packaging and labeling, respectively, prescribed by regulations promulgated under this section.

**(f) Filing of petitions; contents; notice; answer; public hearing; orders**

Any interested person may file with the Administrator[2] a petition proposing the issuance, amendment, or repeal of any regulation contemplated by this section. The petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Administrator[2] shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Administrator[2] shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Administrator[2] shall by order make public his action on such objections. The Administrator[2] shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the

[2] See Transfer of Functions note below.

order detailed findings of fact on which the order is based. The order shall be subject to the provisions of section 371(f) and (g) of this title.

**(g) Records and reports; professional ethics and interests of patients; examination of data; access to records**

(1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed. Regulations and orders issued under this subsection and under clause (3) of subsection (d) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

**(h) Issuance of regulations; conditions; amendment or repeal of regulations; effective date; procedure; lack of substantial evidence**

In the case of a drug for which, on the day immediately preceding May 1, 1963, a prior approval of an application under section 355 of this title had not been withdrawn under section 355(e) of this title, the initial issuance of regulations providing for certification or exemption of such drug under this section shall, with respect to the conditions of use prescribed, recommended, or suggested in the labeling covered by such application, not be conditioned upon an affirmative finding of the efficacy of such drug. Any subsequent amendment or repeal of such regulations so as no longer to provide for such certification or exemption on the ground of a lack of efficacy of such drug for use under such conditions of use may be effected only on or after May 1, 1963, which would be applicable to such drug under such conditions of use if such drug were subject to section 355(e) of this title, and then only if (1) such amendment or repeal is made in accordance with the procedure specified in subsection (f) of this section (except that such amendment or repeal may be initiated either by a proposal of the Secretary or by a petition of any interested person) and (2) the Secretary finds, on the basis of new information with respect to such drug evaluated together with the information before him when the application under section 355 of this title became effective or was approved, that there is a lack of substantial evidence (as defined in section 355(d) of this title) that the drug has the effect it purports or is represented to have under such conditions of use.

(June 25, 1938, ch. 675, §507, as added July 6, 1945, ch. 281, §3, 59 Stat. 463; amended Mar. 10, 1947, ch. 16, §3, 61 Stat. 12; July 13, 1949, ch. 305, §2, 63 Stat. 409; Aug. 5, 1953, ch. 334, §2, 67 Stat. 389; Oct. 10, 1962, Pub. L. 87–781, title I, §§105(a), (b), (d)–(f), 106(a), (b), 76 Stat. 785, 786, 787; July 13, 1968, Pub. L. 90–399, §105(b), 82 Stat. 352; June 16, 1992, Pub. L. 102–300, §6(b)(2), 106 Stat. 240; Aug. 13, 1993, Pub. L. 103–80, §3(p), 107 Stat. 777.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–80, §3(p)(1), substituted ''Secretary'' for ''Federal Security Administrator'' in first sentence and for ''Administrator'' in two other places.

Subsec. (e). Pub. L. 103–80, §3(p)(2), made technical amendment to references to this section to reflect change in references to corresponding provisions of original act and substituted ''Secretary. For purposes'' for ''Secretary: *Provided*, That, for purposes''.

Subsec. (g)(1). Pub. L. 103–80, §3(p)(3), substituted ''repealed. Regulations'' for ''repealed: *Provided, however*, That regulations''.

Subsec. (h). Pub. L. 103–80, §3(p)(4), made technical amendment to reference to this section appearing after ''of such drug under'' to reflect change in reference to corresponding provision of original act.

1992—Subsec. (a). Pub. L. 102–300, which directed the amendment of subsec. (a) by striking out ''of Health, Education, and Welfare'', could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions note below.

1968—Subsec. (a). Pub. L. 90–399 inserted ''(except drugs for use in animals other than man)'' after ''drugs'' in first sentence.

1962—Subsec. (a). Pub. L. 87–781, §105(a), (b), inserted definition of ''antibiotic drug'' and substituted ''bacitracin, or any other antibiotic drug'' for ''or bacitracin''.

Subsec. (c). Pub. L. 87–781, §105(d), required the Secretary to consider, among other relevant factors, whether such drug or class of drugs is manufactured by anyone who has, or shall have, produced 50 consecutive batches in compliance with the regulations for certification, within a period of not more than 18 months, or whether it is manufactured by anyone who has otherwise demonstrated such consistency in production as the Secretary determines is adequate to insure the safety and efficacy thereof, and provided that an exempted manufacturer may still obtain certification of a batch or batches of a drug if he applies for and meets the requirements, and that nothing in this chapter shall be deemed to prevent a truthful statement in labeling or advertising of whether or not the product has been certified or exempted from the requirement of certification.

Subsec. (d). Pub. L. 87–781, §106(b), provided that the regulations may condition the exemption under cl. (3) of this subsection upon the submission of reports of preclinical tests to justify the proposed clinical testing, upon the obtaining by the manufacturer or sponsor of the investigation of a new drug of a signed agreement from each of the investigators that patients to whom the drug is administered will be under his supervision, or under investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings, or upon the establishment and maintenance of records and reports of data obtained by the investiga-

tional use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug, and that the regulations shall condition an exemption upon the manufacturer or sponsor of the investigation requiring that experts using such drugs certify that they will inform humans to whom such drugs or any controls connected therewith are administered, or their representatives, and will obtain the consent of such people where feasible and not against the best interests of such people, and that reports on the investigational use of drugs are not required to be submitted directly to the Secretary.

Subsec. (e). Pub. L. 87–781, § 105(e), subjected new drugs, exempted from the requirements of this section and of section 352(*l*) of this title to section 355 of this title, and provided that for purposes of said section 355, the initial request for certification, as thereafter amended, pursuant to this section, shall be considered a part of the application filed pursuant to section 355(b) of this title with respect to the person filing, and to the drug in question as of the date of the exemption.

Subsec. (g). Pub. L. 87–781, § 106(a), added subsec. (g).

Subsec. (h). Pub. L. 87–781, § 105(f), added subsec. (h).

1953—Act Aug. 5, 1953, § 2(a), substituted ''chlortetracycline'' for ''aureomycin'' in section catchline.

Subsec. (a). Act Aug. 5, 1953, § 2(b), substituted ''chlortetracycline'' for ''aureomycin''.

1949—Act July 13, 1949, § 2(a), inserted ''aureomycin, chloramphenicol, or bacitracin'' in section catchline.

Subsec. (a). Act July 13, 1949, § 2(b), inserted '', aureomycin, chloramphenicol, or bacitracin'' after ''streptomycin''.

1947—Act Mar. 10, 1947, inserted ''or streptomycin'' after ''penicillin'' in section catchline.

Subsec. (a). Act Mar. 10, 1947, inserted ''or streptomycin'' after ''penicillin'' in first sentence.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 335a, 352, 353, 360, 360j, 360aa, 360bb, 360cc, 360ee, 374, 379g of this title; title 26 section 28; title 35 section 156; title 42 section 1396r–8.

## § 358. Authority to designate official names

### (a) Necessity or desirability; use in official compendiums; infringement of trademarks

The Secretary may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this chapter. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

### (b) Review of names in official compendiums

Within a reasonable time after October 10, 1962, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopoeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto) to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

### (c) Determinations of complexity, usefulness, multiplicity, or lack of name; designation by Secretary

Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug or device, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, or to two or more devices which are substantially equivalent in design and purpose or (3) no official name has been applied to a medically useful drug or device, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs or device are identified and recognized his request for the recommendation of a single official name for such drug or drugs or device which will have usefulness and simplicity. Whenever such a single official name has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs or device. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs or device. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 553 of title 5.

### (d) Revised official names; compilation, publication, and public distribution of listings

After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs or devices designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

### (e) Request by compiler of official compendium for designation of name

Upon a request in writing by any compiler of an official compendium that the Secretary exer-

cise the authority granted to him under subsection (a) of this section, he shall upon public notice and in accordance with the procedure set forth in section 553 of title 5 designate the official name of the drug or device for which the request is made.

(June 25, 1938, ch. 675, § 508, as added Oct. 10, 1962, Pub. L. 87–781, title I, § 111(a), 76 Stat. 789; amended May 28, 1976, Pub. L. 94–295, § 5(b), 90 Stat. 581; Aug. 13, 1993, Pub. L. 103–80, § 3(q), 107 Stat. 777.)

AMENDMENTS

1993—Subsecs. (c), (e). Pub. L. 103–80 substituted reference to section 553 of title 5 for ''section 4 of the Administrative Procedure Act (5 U.S.C. 1003)''.

1976—Subsec. (a). Pub. L. 94–295 substituted ''drug or device'' for ''drug'' wherever appearing.

Subsec. (b). Pub. L. 94–295 substituted ''National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)'' for ''National Formulary, and all supplements thereto,''.

Subsec. (c)(2). Pub. L. 94–295 inserted ''or device'' after ''single drug'', and ''or to two or more devices which are substantially equivalent in design and purpose'' after ''purity,''.

Subsec. (c)(3). Pub. L. 94–295 inserted ''or device'' after ''useful drug'' and after ''drug or drugs'' wherever appearing.

Subsec. (d). Pub. L. 94–295 inserted ''or devices'' after ''drugs''.

Subsec. (e). Pub. L. 94–295 substituted ''drug or device'' for ''drug''.

EFFECTIVE DATE

Section 111(b) of Pub. L. 87–781 provided that: ''This section [enacting this section] shall take effect on the date of its enactment [Oct. 10, 1962].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 352 of this title.

## § 359. Nonapplicability of subchapter to cosmetics

This subchapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof.

(June 25, 1938, ch. 675, § 509, as added Oct. 10, 1962, Pub. L. 87–781, title I, § 113, 76 Stat. 791.)

REFERENCES IN TEXT

This subchapter, as amended by the Drug Amendments of 1962, referred to in text, means the amendment of this subchapter by Pub. L. 87–781 which enacted sections 358 to 360 of this title, amended sections 351 to 353, 355, and 357 of this title, and enacted provisions set out as notes under sections 352, 355, 358, and 360 of this title.

The Drug Amendments of 1962, referred to in text, is Pub. L. 87–781, Oct. 10, 1962, 76 Stat. 780, as amended. For complete classification of this Act to the Code, see Short Title of 1962 Amendment note set out under section 301 of this title and Tables.

## § 360. Registration of producers of drugs or devices

### (a) Definitions

As used in this section—

(1) the term ''manufacture, preparation, propagation, compounding, or processing'' shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(2) the term ''name'' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

### (b) Annual registration

On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices shall register with the Secretary his name, places of business, and all such establishments.

### (c) New producers

Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment.

### (d) Additional establishments

Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

### (e) Registration number; uniform system for identification of devices intended for human use

The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j) of this section. Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) of this section shall list such devices in accordance with such system.

### (f) Availability of registrations for inspection

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) of this section and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

### (g) Exclusions from application of section

The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

**(h) Inspection of premises**

Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 374 of this title and every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter.

**(i) Foreign establishments**

Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, or a device or devices, shall be permitted to register under this section pursuant to regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (j) of this section and shall require such establishment to provide the information required by subsection (j) of this section in the case of a device or devices and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether drugs or devices manufactured, prepared, propagated, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 381(a) of this title.

**(j) Filing of lists of drugs and devices manufactured, prepared, propagated and compounded by registrants; statements; accompanying disclosures**

(1) Every person who registers with the Secretary under subsection (b), (c), or (d) of this section shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 352(e) of this title) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug contained in the applicable list and subject to sections 355, 356, 357, or 360b of this title, or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 360d of this title or which is subject to section 360e of this title, a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug or device contained in an applicable list—

(i) which drug is subject to section 353(b)(1) of this title, or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or

(ii) which drug is not subject to section 353(b)(1) of this title or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in an applicable list which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this chapter; and

(D) if the registrant filing a list has determined that a particular drug product or device contained in such list is not subject to section 355, 356, 357, or 360b of this title, or the particular device contained in such list is not subject to a performance standard established under section 360d of this title or to section 360e of this title or is not a restricted device a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product or device.

(2) Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug or device by its established name (as defined in section 352(e) of this title), and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since February 1, 1973) he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by him under subparagraph (A) or paragraph (1); notice of such discontinuance, the date of such discontinuance, and the identity (by established name (as defined in section 352(e) of this title) and by any proprietary name) of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device (each by established name (as defined in section 352(e) of this title) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this chapter.

**(k) Report preceding introduction of devices into interstate commerce**

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

(June 25, 1938, ch. 675, §510, as added Oct. 10, 1962, Pub. L. 87–781, title III, §302, 76 Stat. 794; amended July 15, 1965, Pub. L. 89–74, §4, 79 Stat. 231; Oct. 27, 1970, Pub. L. 91–513, title II, §701(e), 84 Stat. 1282; Aug. 16, 1972, Pub. L. 92–387, §§3, 4(a)–(c), 86 Stat. 560–562; May 28, 1976, Pub. L. 94–295, §4(a), 90 Stat. 579.)

AMENDMENTS

1976—Subsec. (a)(1). Pub. L. 94–295, §4(a)(2), substituted ''drug package or device package'' for ''drug package'', ''distribution of the drug or device'' for ''distribution of the drug'', and ''ultimate consumer or user'' for ''ultimate consumer''.

Subsecs. (b) to (d). Pub. L. 94–295, §4(a)(3), inserted ''or a device or devices'' after ''drug or drugs''.

Subsec. (e). Pub. L. 94–295, §4(a)(4), authorized the Secretary to prescribe by regulation a uniform system for the identification of devices intended for human use and authorized him, in addition, to require that persons who are required to list devices pursuant to subsec. (j) also list such devices in accordance with the system.

Subsec. (g)(1) to (3). Pub. L. 94–295, §4(a)(5), substituted ''drugs or devices'' for ''drugs''.

Subsec. (h). Pub. L. 94–295, §4(a)(6), inserted reference to establishments engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III.

Subsec. (i). Pub. L. 94–295, §4(a)(7), inserted reference to devices and inserted requirement that regulations require establishments to provide the information required by subsection (j) of this section in the case of a device or devices.

Subsec. (j)(1). Pub. L. 94–295, §4(a)(8)(A), in introductory provisions substituted ''a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name'' for ''a list of all drugs (by established name'' and ''drugs or devices filed'' for ''drugs filed''.

Subsec. (j)(1)(A). Pub. L. 94–295, §4(a)(8)(B), substituted ''the applicable list'' for ''such list'', inserted ''or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 360d of this title or which is subject to section 360e of this title,'' after ''360b of this title,'', and substituted ''such drug or device'' for ''such drug'' wherever appearing.

Subsec. (j)(1)(B). Pub. L. 94–295, §4(a)(8)(C), in introductory provisions substituted ''drug or device contained in an applicable list'' for ''drug contained in such list''.

Subsec. (j)(1)(B)(i). Pub. L. 94–295, §4(a)(8)(D), substituted ''which drug is subject to section 353(b)(1) of this title, or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or'' for ''which is subject to section 353(b)(1) of this title, a copy of all labeling for such drug, a representative sampling of advertisements for such drug, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product, or''.

Subsec. (j)(1)(B)(ii). Pub. L. 94–295, §4(a)(8)(E), substituted ''which drug is not subject to section 353(b)(1) of this title or which device is not a restricted device,

the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device'' for ''which is not subject to section 353(b)(1) of this title, the label and package insert for such drug and a representative sampling of any other labeling for such drug''.

Subsec. (j)(1)(C). Pub. L. 94–295, § 4(a)(8)(F), substituted ''an applicable list'' for ''such list''.

Subsec. (j)(1)(D). Pub. L. 94–295, § 4(a)(8)(G), substituted ''a list'' for ''the list'', inserted ''or the particular device contained in such list is not subject to a performance standard established under section 360d of this title or to section 360e of this title or is not a restricted device'' after ''or 360b of this title,'', and substituted ''particular drug product or device'' for ''particular drug product'' wherever appearing.

Subsec. (j)(2). Pub. L. 94–295, § 4(a)(8)(H), substituted ''drug or ''device'' for ''drug'' in subpars. (A), (B), and (C), and substituted ''(each by established name'' for ''(by established name'' in subpar. (C).

Subsec. (k). Pub. L. 94–295, § 4(a)(9), added subsec. (k).

1972—Subsec. (e). Pub. L. 92–387, § 4(a), inserted provision that the Secretary may assign a listing number to each drug or class of drugs listed under subsec. (j).

Subsec. (f). Pub. L. 92–387, § 4(b), inserted exception that the list submitted under subsec. (j)(3) and information submitted under subsec. (j)(1), (2) shall be exempt from inspection unless the Secretary determines otherwise.

Subsec. (i). Pub. L. 92–387, § 4(c), inserted provision that the regulations shall require such establishment to provide the information required by subsec. (j).

Subsec. (j). Pub. L. 92–387, § 3, added subsec. (j).

1970—Subsec. (a). Pub. L. 91–513 struck out provisions defining the wholesaling, jobbing, or distributing of depressant or stimulant drugs.

Subsec. (b). Pub. L. 91–513 struck out provisions covering establishments engaged in the wholesaling, jobbing, or distributing of depressant or stimulant drugs and the inclusion of the fact of such activity in the annual registration.

Subsec. (c). Pub. L. 91–513 struck out provisions covering new registrations of persons first engaging in the wholesaling, jobbing, or distributing of depressant or stimulant drugs and the inclusion of the fact of such activity in the registration.

Subsec. (d). Pub. L. 91–513 struck out number designation ''(1)'' preceding first sentence, struck out portion of such redesignated provisions covering the wholesaling, jobbing, or distributing of depressant or stimulant drugs, and struck out par. (2) covering the filing of supplemental registration whenever a person not previously engaged or involved with depressant or stimulant drugs goes into the manufacturing, preparation, or processing thereof.

1965—Pub. L. 89–74, § 4(e), included certain wholesalers in section catchline.

Subsec. (a)(2), (3). Pub. L. 89–74, § 4(a), added par. (2) and redesignated former par. (2) as (3).

Subsecs. (b), (c). Pub. L. 89–74, § 4(b), (c), inserted ''or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug'' after ''drug or drugs'' and inserted requirement that establishment indicate activity in depressant or stimulant drugs at time of registration.

Subsec. (d). Pub. L. 89–74 § 4(d), designated existing provisions as par. (1), inserted ''or the wholesaling, jobbing, or distributing of any depressant or stimulant drug'' and the requirement that the additional establishment indicate activity in depressant or stimulant drugs at time of registration, and added par. (2).

EFFECTIVE DATE OF 1972 AMENDMENT

Section 5 of Pub. L. 92–387 provided that: ''The amendments made by this Act [amending this section and sections 331 and 335 of this title and enacting provisions set out below] shall take effect on the first day of the sixth month beginning after the date of enactment of this Act [Aug. 16, 1972].''

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective Feb. 1, 1966, subject to registration with Secretary of names, places of business, establishments, and other prescribed information prior to Feb. 1, 1966, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

CONGRESSIONAL DECLARATION OF NEED FOR REGISTRATION AND INSPECTION OF DRUG ESTABLISHMENTS

Section 301 of Pub. L. 87–781 provided that: ''The Congress hereby finds and declares that in order to make regulation of interstate commerce in drugs effective, it is necessary to provide for registration and inspection of all establishments in which drugs are manufactured, prepared, propagated, compounded, or processed; that the products of all such establishments are likely to enter the channels of interstate commerce and directly affect such commerce; and that the regulation of interstate commerce in drugs without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs would discriminate against and depress interstate commerce in such drugs, and adversely burden, obstruct, and affect such interstate commerce.''

DECLARATION OF POLICY OF DRUG LISTING ACT OF 1972

Section 2 of Pub. L. 92–387 provided that: ''The Federal Government which is responsible for regulating drugs has no ready means of determining what drugs are actually being manufactured or packed by establishments registered under the Federal Food, Drug, and Cosmetic Act [this chapter] except by periodic inspection of such registered establishments. Knowledge of which particular drugs are being manufactured or packed by each registered establishment would substantially assist in the enforcement of Federal laws requiring that such drugs be pure, safe, effective, and properly labeled. Information on the discontinuance of a particular drug could serve to alleviate the burden of reviewing and implementing enforcement actions against drugs which, although commercially discontinued, remain active for regulatory purposes. Information on the type and number of different drugs being manufactured or packed by drug establishments could permit more effective and timely regulation by the agencies of the Federal Government responsible for regulating drugs, including identification of which drugs in interstate commerce are subject to section 505 or 507 [section 355 or 357 of this title], or to other provisions of the Federal Food, Drug, and Cosmetic Act.''

REGISTRATION OF CERTAIN PERSONS OWNING OR OPERATING DRUG ESTABLISHMENTS PRIOR TO OCT. 10, 1962

Section 303 of Pub. L. 87–781 provided that any person who, on the day immediately preceding Oct. 10, 1962, owned or operated an establishment which manufactured or processed drugs, registered before the first day of the seventh month following October, 1962, would be deemed to be registered in accordance with subsec. (b)

of this section for the calendar year 1962 and if registered within this period and effected in 1963, be deemed in compliance for that calendar year.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 355, 360c, 360e, 360i, 360j, 379h, 381 of this title.

### § 360a. Repealed. Pub. L. 91–513, title II, § 701(a), Oct. 27, 1970, 84 Stat. 1281

Section, act June 25, 1938, ch. 675, § 511, as added July 15, 1965, Pub. L. 89–74, § 3(b), 79 Stat. 227; amended Oct. 24, 1968, Pub. L. 90–639, § 2(a), 82 Stat. 1361, regulated the manufacture, compounding, and processing of depressant and stimulant drugs and their sale, delivery, disposal, possession, and recordkeeping activities connected therewith. See section 801 et seq. of this title.

EFFECTIVE DATE OF REPEAL

Repeal by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

SAVINGS PROVISION

Repeal not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such repeal, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

### § 360b. New animal drugs

#### (a) Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research

(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) and section 342(a)(2)(D) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug, and

(B) such drug, its labeling, and such use conform to such approved application.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee—

(i) is the holder of an approved application under subsection (m) of this section; or

(ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under subsection (m) of this section.

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed, be deemed unsafe for the purposes of section 351(a)(6) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drugs, as used in such animal feed,

(B) there is in effect an approval of an application pursuant to subsection (m)(1) of this section with respect to such animal feed, and

(C) such animal feed, its labeling, and such use conform to the conditions and indications of use published pursuant to subsection (i) of this section and to the application with respect thereto approved under subsection (m) of this section.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 351(a)(5) or (6) of this title if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under subsection (j) of this section.

(4)(A) Except as provided in subparagraph (B), if an approval of an application filed under subsection (b) of this section is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of paragraph (1) and shall be exempt from the requirements of section 352(f) of this title with respect to a different use or intended use of the drug, other than a use in or on animal feed, if such use or intended use—

(i) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(ii) is in compliance with regulations promulgated by the Secretary that establish the conditions for such different use or intended use.

The regulations promulgated by the Secretary under clause (ii) may prohibit particular uses of an animal drug and shall not permit such different use of an animal drug if the labeling of another animal drug that contains the same active ingredient and which is in the same dosage form and concentration provides for such different use.

(B) If the Secretary finds that there is a reasonable probability that a use of an animal drug authorized under subparagraph (A) may present a risk to the public health, the Secretary may—

(i) establish a safe level for a residue of an animal drug when it is used for such different use authorized by subparagraph (A); and

(ii) require the development of a practical, analytical method for the detection of residues of such drug above the safe level established under clause (i).

The use of an animal drug that results in residues exceeding a safe level established under clause (i) shall be considered an unsafe use of such drug under paragraph (1). Safe levels may be established under clause (i) either by regulation or order.

(C) The Secretary may by general regulation provide access to the records of veterinarians to ascertain any use or intended use authorized under subparagraph (A) that the Secretary has determined may present a risk to the public health.

(D) If the Secretary finds, after affording an opportunity for public comment, that a use of an animal drug authorized under subparagraph (A) presents a risk to the public health or that an analytical method required under subparagraph (B) has not been developed and submitted to the Secretary, the Secretary may, by order, prohibit any such use.

(5) If the approval of an application filed under section 355 of this title is in effect, the drug under such application shall not be deemed unsafe for purposes of paragraph (1) and shall be exempt from the requirements of section 352(f) of this title with respect to a use or intended use of the drug in animals if such use or intended use—

(A) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(B) is in compliance with regulations promulgated by the Secretary that establish the conditions for the use or intended use of the drug in animals.

**(b) Filing application for uses of new animal drug; contents; patent information; abbreviated application**

(1) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (G) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (H) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe. The applicant shall file with the application the patent number and the expiration date of any patent which claims the new animal drug for which the applicant filed the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.

(2) Any person may file with the Secretary an abbreviated application for the approval of a new animal drug. An abbreviated application shall contain the information required by subsection (n) of this section.

**(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order; abbreviated applications; withdrawal periods; effective date of approval; relationship to other applications; withdrawal or suspension of approval; bioequivalence; filing of additional patent information**

(1) Within one hundred and eighty days after the filing of an application pursuant to subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (A) issue an order approving the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for a hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2)(A) Subject to subparagraph (C), the Secretary shall approve an abbreviated application for a drug unless the Secretary finds—

(i) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(ii) the conditions of use prescribed, recommended, or suggested in the proposed labeling are not reasonably certain to be followed in practice or, except as provided in subparagraph (B), information submitted with the application is insufficient to show that each of the proposed conditions of use or similar limitations (whether in the labeling or published pursuant to subsection (i) of this section) have been previously approved for the approved new animal drug referred to in the application;

(iii) information submitted with the application is insufficient to show that the active ingredients are the same as those of the approved new animal drug referred to in the application;

(iv)(I) if the application is for a drug whose active ingredients, route of administration, dosage form, strength, or use with other ani-

mal drugs in animal feed is the same as the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed of the approved new animal drug referred to in the application, information submitted in the application is insufficient to show that the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is the same as that of the approved new animal drug, or

(II) if the application is for a drug whose active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is different from that of the approved new animal drug referred to in the application, no petition to file an application for the drug with the different active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed was approved under subsection (n)(3) of this section;

(v) if the application was filed pursuant to the approval of a petition under subsection (n)(3) of this section, the application did not contain the information required by the Secretary respecting the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed which is not the same;

(vi) information submitted in the application is insufficient to show that the drug is bioequivalent to the approved new animal drug referred to in the application, or if the application is filed under a petition approved pursuant to subsection (n)(3) of this section, information submitted in the application is insufficient to show that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug and that the new animal drug can be expected to have the same therapeutic effect as the approved new animal drug when used in accordance with the labeling;

(vii) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the approved new animal drug referred to in the application except for changes required because of differences approved under a petition filed under subsection (n)(3) of this section, because of a different withdrawal period, or because the drug and the approved new animal drug are produced or distributed by different manufacturers;

(viii) information submitted in the application or any other information available to the Secretary shows that (I) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, (II) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included, or (III) in the case of a drug for food producing animals, the inactive ingredients of the drug or its composition may be unsafe with respect to human food safety;

(ix) the approval under subsection (b)(1) of this section of the approved new animal drug referred to in the application filed under subsection (b)(2) of this section has been withdrawn or suspended for grounds described in paragraph (1) of subsection (e) of this section, the Secretary has published a notice of a hearing to withdraw approval of the approved new animal drug for such grounds, the approval under this paragraph of the new animal drug for which the application under subsection (b)(2) of this section was filed has been withdrawn or suspended under subparagraph (G) for such grounds, or the Secretary has determined that the approved new animal drug has been withdrawn from sale for safety or effectiveness reasons;

(x) the application does not meet any other requirement of subsection (n) of this section; or

(xi) the application contains an untrue statement of material fact.

(B) If the Secretary finds that a new animal drug for which an application is submitted under subsection (b)(2) of this section is bioequivalent to the approved new animal drug referred to in such application and that residues of the new animal drug are consistent with the tolerances established for such approved new animal drug but at a withdrawal period which is different than the withdrawal period approved for such approved new animal drug, the Secretary may establish, on the basis of information submitted, such different withdrawal period as the withdrawal period for the new animal drug for purposes of the approval of such application for such drug.

(C) Within 180 days of the initial receipt of an application under subsection (b)(2) of this section or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(D) The approval of an application filed under subsection (b)(2) of this section shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in clause (i) or (ii) of subsection (n)(1)(G) of this section or in both such clauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in clause (iii) of subsection (n)(1)(G) of this section, the approval may be made effective on the date certified under clause (iii).

(iii) If the applicant made a certification described in clause (iv) of subsection (n)(1)(G) of this section, the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of 45 days from the date the notice provided under subsection (n)(2)(B)(i) of this section is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the 30 month period beginning on the date of the receipt of the notice provided under subsection (n)(2)(B) of this section or such shorter or longer period as the court may order because

either party to the action failed to reasonably cooperate in expediting the action, except that if before the expiration of such period—

(I) the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or

(III) the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of 45 days from the date the notice made under subsection (n)(2)(B) of this section is received, no action may be brought under section 2201 of title 28 for a declaratory judgment with respect to the patent. Any action brought under section 2201 of title 28 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in clause (iv) of subsection (n)(1)(G) of this section and is for a drug for which a previous application has been filed under this subsection containing such a certification, the application shall be made effective not earlier than 180 days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in subclause (III)[1] holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within 30 days after such notice, such hearing shall commence not more than 90 days after the expiration of such 30 days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within 90 days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application submitted under subsection (b)(1) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b)(1) of this section, is approved after November 16, 1988, no application may be submitted under subsection (b)(2) of this section which refers to the drug for which the subsection (b)(1) application was submitted before the expiration of 5 years from the date of the approval of the application under subsection (b)(1) of this section, except that such an application may be submitted under subsection (b)(2) of this section after the expiration of 4 years from the date of the approval of the subsection (b)(1) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (n)(1)(G) of this section. The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning 48 months after the date of the approval of the subsection (b) application, the 30 month period referred to in subparagraph (D)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(ii) If an application submitted under subsection (b)(1) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under such subsection, is approved after November 16, 1988, and if such application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) and, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b)(2) of this section for the conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of 3 years from the date of the approval of the application under subsection (b)(1) of this section for such drug.

(iii) If a supplement to an application approved under subsection (b)(1) of this section is approved after November 16, 1988, and the supplement contains reports of new clinical or field investigations (other than bioequivalence or residue studies) and, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b)(2) of this section for a change approved in the supplement effective before the expiration of 3 years from the date of the approval of the supplement.

(iv) An applicant under subsection (b)(1) of this section who comes within the provisions of clause (i) of this subparagraph as a result of an application which seeks approval for a use solely in non-food producing animals, may elect, within 10 days of receiving such approval, to waive clause (i) of this subparagraph, in which event the limitation on approval of applications submitted under subsection (b)(2) of this section set forth in clause (ii) of this subparagraph shall be applicable to the subsection (b)(1) application.

[1] So in original. Probably should be "clause (iii)(III)".

(v) If an application (including any supplement to a new animal drug application) submitted under subsection (b)(1) of this section for a new animal drug for a food-producing animal use, which includes an active ingredient (including any ester or salt of the active ingredient) which has been the subject of a waiver under subparagraph (B)(iv) is approved after November 16, 1988, and if the application contains reports of clinical or field investigations or human food safety studies (other than bioequivalence or residue studies) essential to the new approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application (including any supplement to such application) submitted under subsection (b)(2) of this section for the new conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of five years from the date of approval of the application under subsection (b)(1) of this section for such drug. The provisions of this paragraph shall apply only to the first approval for a food-producing animal use for the same applicant after the waiver under subparagraph (B)(iv).

(G) If an approved application submitted under subsection (b)(2) of this section for a new animal drug refers to a drug the approval of which was withdrawn or suspended for grounds described in paragraph (1) or (2) of subsection (e) of this section or was withdrawn or suspended under this subparagraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this paragraph shall be withdrawn or suspended—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or this subparagraph, or

(ii) if the approved new animal drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(H) For purposes of this paragraph:

(i) The term ''bioequivalence'' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a new animal drug and becomes available at the site of drug action.

(ii) A new animal drug shall be considered to be bioequivalent to the approved new animal drug referred to in its application under subsection (n) of this section if—

(I) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses;

(II) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the approved new animal drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective drug concentrations in use, and is considered scientifically insignificant for the drug in attaining the intended purposes of its use and preserving human food safety; or

(III) in any case in which the Secretary determines that the measurement of the rate and extent of absorption or excretion of the new animal drug in biological fluids is inappropriate or impractical, an appropriate acute pharmacological effects test or other test of the new animal drug and, when deemed scientifically necessary, of the approved new animal drug referred to in the application in the species to be tested or in an appropriate animal model does not show a significant difference between the new animal drug and such approved new animal drug when administered at the same dose under similar experimental conditions.

If the approved new animal drug referred to in the application for a new animal drug under subsection (n) of this section is approved for use in more than one animal species, the bioequivalency information described in subclauses (I), (II), and (III) shall be obtained for one species, or if the Secretary deems appropriate based on scientific principles, shall be obtained for more than one species. The Secretary may prescribe the dose to be used in determining bioequivalency under subclause (I), (II), or (III). To assure that the residues of the new animal drug will be consistent with the established tolerances for the approved new animal drug referred to in the application under subsection (b)(2) of this section upon the expiration of the withdrawal period contained in the application for the new animal drug, the Secretary shall require bioequivalency data or residue depletion studies of the new animal drug or such other data or studies as the Secretary considers appropriate based on scientific principles. If the Secretary requires one or more residue studies under the preceding sentence, the Secretary may not require that the assay methodology used to determine the withdrawal period of the new animal drug be more rigorous than the methodology used to determine the withdrawal period for the approved new animal drug referred to in the application. If such studies are required and if the approved new animal drug, referred to in the application for the new animal drug for which such studies are required, is approved for use in more than one animal species, such studies shall be conducted for one species, or if the Secretary deems appropriate based on scientific principles, shall be conducted for more than one species.

(3) If the patent information described in subsection (b)(1) of this section could not be filed with the submission of an application under subsection (b)(1) of this section because the application was filed before the patent information was required under subsection (b)(1) of this section or a patent was issued after the application was

approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the new animal drug for which the application was filed or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b)(1) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than 30 days after November 16, 1988, and if the holder of an approved application could not file patent information under subsection (b)(1) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than 30 days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

**(d) Grounds for refusing application; approval of application; factors; "substantial evidence" defined**

(1) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that—

(A) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(B) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(D) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions;

(E) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(F) upon the basis of the information submitted to him as part of the application or any other information before him with respect to such drug, the tolerance limitation proposed, if any, exceeds that reasonably required to accomplish the physical or other technical effect for which the drug is intended;

(G) the application failed to contain the patent information prescribed by subsection (b)(1) of this section;

(H) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; or

(I) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h) of this section), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearings, the Secretary finds that subparagraphs (A) through (I) do not apply, he shall issue an order approving the application.

(2) In determining whether such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the Secretary shall consider, among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice. Any order issued under this subsection refusing to approve an application shall state the findings upon which it is based.

(3) As used in this subsection and subsection (e) of this section, the term ''substantial evidence'' means evidence consisting of adequate and well-controlled investigations, including field investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

**(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals**

(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application

filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds—

(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved or the condition of use authorized under subsection (a)(4)(A) of this section;

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) of this section applies to such drug;

(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(D) the patent information prescribed by subsection (c)(3) of this section was not filed within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information;

(E) that the application contains any untrue statement of a material fact; or

(F) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds—

(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under subsection (1) of this section, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(3) Any order under this subsection shall state the findings upon which it is based.

**(f) Revocation of order refusing, withdrawing or suspending approval of application**

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d), (e), or (m) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

**(g) Service of orders**

Orders of the Secretary issued under this section (other than orders issuing, amending, or repealing regulations) shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last known address in the records of the Secretary.

**(h) Appeal from order**

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application filed under subsection (b) or (m) of this section. The provisions of subsection (h) of section 355 of this title shall govern any such appeal.

**(i) Publication in Federal Register; effective date and revocation or suspension of regulation**

When a new animal drug application filed pursuant to subsection (b) of this section is approved, the Secretary shall by notice, which upon publication shall be effective as a regulation, publish in the Federal Register the name and address of the applicant and the conditions and indications of use of the new animal drug covered by such application, including any tolerance and withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed for use in which such drug is approved, and such other information, upon the basis of which such application was approved, as the Secretary

deems necessary to assure the safe and effective use of such drug. Upon withdrawal of approval of such new animal drug application or upon its suspension, the Secretary shall forthwith revoke or suspend, as the case may be, the regulation published pursuant to this subsection (i) insofar as it is based on the approval of such application.

**(j) Exemption of drugs for research; discretionary and mandatory conditions**

To the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of this section new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. Such regulations may, in the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable him to evaluate the safety and effectiveness of such article in the event of the filing of an application pursuant to this section. Such regulations, among other things, shall set forth the conditions (if any) upon which animals treated with such articles, and any products of such animals (before or after slaughter), may be marketed for food use.

**(k) Food containing new animal drug considered unadulterated while approval of application for such drug is effective**

While approval of an application for a new animal drug is effective, a food shall not, by reason of bearing or containing such drug or any substance formed in or on the food because of its use in accordance with such application (including the conditions and indications of use prescribed pursuant to subsection (i) of this section), be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

**(*l*) Records and reports; required information; regulations and orders; examination of data; access to records**

(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A) of this section, and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

**(m)(1) Filing application for uses of animal feed containing new animal drug; contents**

Any person may file with the Secretary an application with respect to any intended use or uses of an animal feed bearing or containing a new animal drug. Such person shall submit to the Secretary as part of the application (A) a full statement of the composition of such animal feed, (B) an identification of the regulation or regulations (relating to the new animal drug or drugs to be used in such feed), published pursuant to subsection (i) of this section, on which he relies as a basis for approval of his application with respect to the use of such drug in such feed, (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed, (D) specimens of the labeling proposed to be used for such animal feed, and (E) if so requested by the Secretary, samples of such animal feed or components thereof.

**(2) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order**

Within ninety days after the filing of an application pursuant to paragraph (1) of this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (A) issue an order approving the application if he then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c) of this section.

**(3) Grounds for refusing application; approval of application; approval effective during existence of subsection (i) regulation**

If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving him an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to him as part of the application or on the basis of any other information before him—

(A) that there is not in effect a regulation under subsection (i) of this section (identified in such application) on the basis of which such application may be approved;

(B) that such animal feed (including the proposed use of any new animal drug therein or

thereon) does not conform to an applicable regulation published pursuant to subsection (i) of this section referred to in the application, or that the purposes and conditions or indications of use prescribed, recommended, or suggested in the labeling of such feed do not conform to the applicable purposes and conditions or indications of use (including warnings) published pursuant to subsection (i) of this section or such labeling omits or fails to conform to other applicable information published pursuant to subsection (i) of this section;

(C) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(D) that, based on a fair evaluation of all material facts, such labeling is false or misleading in any particular;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (D) do not apply, he shall issue an order approving the application. An order under this subsection approving an application with respect to an animal feed bearing or containing a new animal drug shall be effective only while there is in effect a regulation pursuant to subsection (i) of this section, on the basis of which such application (or a supplement thereto) was approved, relating to the use of such drug in or on such feed.

**(4) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals**

(A) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application with respect to any animal feed under this subsection if the Secretary finds—

(i) that the application contains any untrue statement of a material fact; or

(ii) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any animal feed under this subsection if the Secretary finds—

(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5)(A) of this subsection, or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph;

(ii) that on the basis of new information before him, evaluated together with the evidence before him when such application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of; or

(iii) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such animal feed, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(C) Any order under paragraph (4) of this subsection shall state the findings upon which it is based.

**(5) Records and reports; regulations and orders; access to records**

In the case of an animal feed for which an approval of an application filed pursuant to this subsection is in effect—

(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b) of this section, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section or paragraph (4) of this subsection.

(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

**(n) Abbreviated applications for new animal drugs; contents, filing, etc.; lists of approved drugs**

(1) An abbreviated application for a new animal drug shall contain—

(A)(i) except as provided in clause (ii), information to show that the conditions of use or similar limitations (whether in the labeling or published pursuant to subsection (i) of this section) prescribed, recommended, or sug-

gested in the labeling proposed for the new animal drug have been previously approved for a new animal drug listed under paragraph (4) (hereinafter in this subsection referred to as an ''approved new animal drug''), and

(ii) information to show that the withdrawal period at which residues of the new animal drug will be consistent with the tolerances established for the approved new animal drug is the same as the withdrawal period previously established for the approved new animal drug or, if the withdrawal period is proposed to be different, information showing that the residues of the new animal drug at the proposed different withdrawal period will be consistent with the tolerances established for the approved new animal drug;

(B)(i) information to show that the active ingredients of the new animal drug are the same as those of the approved new animal drug, and

(ii) if the approved new animal drug has more than one active ingredient, and if one of the active ingredients of the new animal drug is different from one of the active ingredients of the approved new animal drug and the application is filed pursuant to the approval of a petition filed under paragraph (3)—

(I) information to show that the other active ingredients of the new animal drug are the same as the active ingredients of the approved new animal drug,

(II) information to show either that the different active ingredient is an active ingredient of another approved new animal drug or of an animal drug which does not meet the requirements of section 321(v) of this title, and

(III) such other information respecting the different active ingredients as the Secretary may require;

(C)(i) if the approved new animal drug is permitted to be used with one or more animal drugs in animal feed, information to show that the proposed uses of the new animal drug with other animal drugs in animal feed are the same as the uses of the approved new animal drug, and

(ii) if the approved new animal drug is permitted to be used with one or more other animal drugs in animal feed, and one of the other animal drugs proposed for use with the new animal drug in animal feed is different from one of the other animal drugs permitted to be used in animal feed with the approved new animal drug, and the application is filed pursuant to the approval of a petition filed under paragraph (3)—

(I) information to show either that the different animal drug proposed for use with the approved new animal drug in animal feed is an approved new animal drug permitted to be used in animal feed or does not meet the requirements of section 321(v) of this title when used with another animal drug in animal feed,

(II) information to show that other animal drugs proposed for use with the new animal drug in animal feed are the same as the other animal drugs permitted to be used with the approved new animal drug, and

(III) such other information respecting the different animal drug or combination with respect to which the petition was filed as the Secretary may require,

(D) information to show that the route of administration, the dosage form, and the strength of the new animal drug are the same as those of the approved new animal drug or, if the route of administration, the dosage form, or the strength of the new animal drug is different and the application is filed pursuant to the approval of a petition filed under paragraph (3), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(E) information to show that the new animal drug is bioequivalent to the approved new animal drug, except that if the application is filed pursuant to the approval of a petition filed under paragraph (3) for the purposes described in subparagraph (B) or (C), information to show that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug and that the new animal drug can be expected to have the same therapeutic effect as the approved new animal drug when used in accordance with the labeling;

(F) information to show that the labeling proposed for the new animal drug is the same as the labeling approved for the approved new animal drug except for changes required because of differences approved under a petition filed under paragraph (3), because of a different withdrawal period, or because the new animal drug and the approved new animal drug are produced or distributed by different manufacturers;

(G) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(H) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the approved new animal drug or which claims a use for such approved new animal drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b)(1) or (c)(3) of this section—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new animal drug for which the application is filed; and

(I) if with respect to the approved new animal drug information was filed under subsection (b)(1) or (c)(3) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval of an application under subsection (c)(2) of this section, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addi-

tion to that required by subparagraphs (A) through (I).

(2)(A) An applicant who makes a certification described in paragraph (1)(G)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved application under subsection (c)(1) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application, which contains data from bioequivalence studies, has been filed under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (1)(G)(iv), the notice required by subparagraph (B) shall be given when the amended application is filed.

(3) If a person wants to submit an abbreviated application for a new animal drug—

(A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or

(B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug,

such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve a petition for a new animal drug unless the Secretary finds that—

(C) investigations must be conducted to show the safety and effectiveness, in animals to be treated with the drug, of the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed which differ from the approved new animal drug, or

(D) investigations must be conducted to show the safety for human consumption of any residues in food resulting from the proposed active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed for the new animal drug which is different from the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed of the approved new animal drug.

The Secretary shall approve or disapprove a petition submitted under this paragraph within 90 days of the date the petition is submitted.

(4)(A)(i) Within 60 days of November 16, 1988, the Secretary shall publish and make available to the public a list in alphabetical order of the official and proprietary name of each new animal drug which has been approved for safety and effectiveness before November 16, 1988.

(ii) Every 30 days after the publication of the first list under clause (i) the Secretary shall revise the list to include each new animal drug which has been approved for safety and effectiveness under subsection (c) of this section during the 30 day period.

(iii) When patent information submitted under subsection (b)(1) or (c)(3) of this section respecting a new animal drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A new animal drug approved for safety and effectiveness before November 16, 1988, or approved for safety and effectiveness under subsection (c) of this section shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or November 16, 1988, whichever is later.

(C) If the approval of a new animal drug was withdrawn or suspended under subsection (c)(2)(G) of this section or for grounds described in subsection (e) of this section or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (c)(2)(G) or (e) of this section, or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(5) If an application contains the information required by clauses (A), (G), and (H) of subsection (b)(1) of this section and such information—

(A) is relied on by the applicant for the approval of the application, and

(B) is not information derived either from investigations, studies, or tests conducted by or for the applicant or for which the applicant had obtained a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted,

such application shall be considered to be an application filed under subsection (b)(2) of this section.

**(*o*) "Patent" defined**

For purposes of this section, the term ''patent'' means a patent issued by the Patent and Trademark Office of the Department of Commerce.

**(p) Safety and effectiveness data**

(1) Safety and effectiveness data and information which has been submitted in an application filed under subsection (b)(1) of this section for a drug and which has not previously been dis-

closed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) of this section is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application filed under subsection (b)(2) of this section which refers to such drug or upon the date upon which the approval of an application filed under subsection (b)(2) of this section which refers to such drug could be made effective if such an application had been filed.

(2) Any request for data and information pursuant to paragraph (1) shall include a verified statement by the person making the request that any data or information received under such paragraph shall not be disclosed by such person to any other person—

(A) for the purpose of, or as part of a plan, scheme, or device for, obtaining the right to make, use, or market, or making, using, or marketing, outside the United States, the drug identified in the application filed under subsection (b)(1) of this section, and

(B) without obtaining from any person to whom the data and information are disclosed an identical verified statement, a copy of which is to be provided by such person to the Secretary, which meets the requirements of this paragraph.

(June 25, 1938, ch. 675, § 512, as added July 13, 1968, Pub. L. 90–399, § 101(b), 82 Stat. 343; amended Nov. 16, 1988, Pub. L. 100–670, title I, §§ 101, 102, 104, 107(a)(2), 102 Stat. 3971, 3981, 3982, 3984; Aug. 17, 1991, Pub. L. 102–108, § 2(e), 105 Stat. 550; Aug. 13, 1993, Pub. L. 103–80, § 3(r), 107 Stat. 777; Oct. 22, 1994, Pub. L. 103–396, § 2(a), (b)(2), (3), 108 Stat. 4153, 4154.)

AMENDMENTS

1994—Subsec. (a)(4), (5). Pub. L. 103–396, § 2(a), added pars. (4) and (5).

Subsec. (e)(1)(A). Pub. L. 103–396, § 2(b)(2), inserted before semicolon at end ''or the condition of use authorized under subsection (a)(4)(A) of this section''.

Subsec. (*l*)(1). Pub. L. 103–396, § 2(b)(3), substituted ''relating to experience, including experience with uses authorized under subsection (a)(4)(A) of this section,'' for ''relating to experience''.

1993—Subsec. (c)(2)(A)(ii). Pub. L. 103–80, § 3(r)(1), inserted ''in'' after ''except as provided''.

Subsec. (c)(2)(F)(i). Pub. L. 103–80, § 3(r)(2), substituted ''subparagraph (D)(iii)'' for ''subparagraph (C)(iii)''.

Subsec. (c)(2)(H)(ii). Pub. L. 103–80, § 3(r)(3), substituted ''subclauses'' for ''subclause'' after ''bioequivalency information described in'' in concluding provisions.

Subsec. (d)(1). Pub. L. 103–80, § 3(r)(4), substituted ''subparagraphs (A) through (I)'' for ''subparagraphs (A) through (G)'' in concluding provisions.

Subsec. (n)(1). Pub. L. 103–80, § 3(r)(5), substituted ''section 321(v) of this title'' for ''section 321(w) of this title'' in subpars. (B)(ii)(II) and (C)(ii)(I) and substituted ''through (I)'' for ''through (H)'' in concluding provisions.

1991—Subsec. (e)(1)(B). Pub. L. 102–108 substituted ''(I)'' for ''(H)''.

1988—Subsec. (a)(1)(C). Pub. L. 100–670, § 107(a)(2), struck out subpar. (C) which read as follows: ''in the case of a new animal drug subject to subsection (n) of this section and not exempted therefrom by regulations it is from a batch with respect to which a certificate or release issued pursuant to subsection (n) of this section is in effect with respect to such drug.''

Subsec. (b). Pub. L. 100–670, §§ 101(a), 102(a), designated existing provisions as par. (1), redesignated cls. (1) to (8) as cls. (A) to (H), respectively, added par. (2), and inserted provisions at end of par. (1) which require applicant to file with application, patent number and expiration date of any patent which claims new animal drug, to amend application to include such information if patent which claims such drug or method of using such drug is issued after filing date but before approval of application, and to publish such information upon approval.

Subsec. (c). Pub. L. 100–670, §§ 101(c), 102(b)(1), designated existing provisions as par. (1), redesignated cls. (1) and (2) as cls. (A) and (B), respectively, and added pars. (2) and (3).

Subsec. (d)(1). Pub. L. 100–670, § 102(b)(3), substituted ''(G)'' for ''(H)'' in last sentence.

Subsec. (d)(1)(G) to (I). Pub. L. 100–670, § 102(b)(2), added subpar. (G) and redesignated former subpars. (G) and (H) as (H) and (I), respectively.

Subsec. (e)(1)(D) to (F). Pub. L. 100–670, § 102(b)(4), added subpar. (D) and redesignated former subpars. (D) and (E) as (E) and (F), respectively.

Subsecs. (n) to (p). Pub. L. 100–670, § 101(b), added subsecs. (n) to (p) and struck out former subsec. (n) which related to certification of new drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, and release prior to certification.

EFFECTIVE DATE OF 1994 AMENDMENT

Section 2(d) of Pub. L. 103–396 provided that: ''The amendments made by this section [amending this section and section 331 of this title] shall take effect upon the adoption of the final regulations under subsection (c) [set out below].''

EFFECTIVE DATE OF 1988 AMENDMENT

Section 108 of Pub. L. 100–670 provided that: ''The Secretary of Health and Human Services may not make an approval of an application submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2)) effective before January 1, 1991.''

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

Section 108 of Pub. L. 90–399 provided that:

''(a) Except as otherwise provided in this section, the amendments made by the foregoing sections [see Short Title of 1968 Amendment note set out under section 301 of this title] shall take effect on the first day of the thirteenth calendar month which begins after the date of enactment of this Act [July 13, 1968].

''(b)(1) As used in this subsection, the term 'effective date' means the effective date specified in subsection (a) of this section; the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter]; and other terms used both in this section and the basic Act shall have the same meaning as they have, or had, at the time referred to in the context, under the basic Act.

''(2) Any approval, prior to the effective date, of a new animal drug or of an animal feed bearing or containing a new animal drug, whether granted by approval of a new-drug application, master file, antibiotic regulation, or food additive regulations, shall continue in effect, and shall be subject to change in accordance with the provisions of the basic Act as amended by this Act [see Short Title of 1968 Amendment note set out under section 301 of this title].

''(3) In the case of any drug (other than a drug subject to section 512(n) of the basic Act as amended by this

Act) [subsection (n) of this section] intended for use in animals other than man which, on October 9, 1962, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act [section 321(p) of this title] as then in force, and (C) was not covered by an effective application under section 505 of that Act [section 355 of this title], the words 'effectiveness' and 'effective' contained in section 201(w) as added by this Act to the basic Act [section 321(w) of this title] shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

''(4) Regulations providing for fees (and advance deposits to cover fees) which on the day preceding the effective date applicable under subsection (a) of this section were in effect pursuant to section 507 of the basic Act [section 357 of this title] shall, except as the Secretary may otherwise prescribe, be deemed to apply also under section 512(n) of the basic Act [subsection (n) of this section], and appropriations of fees (and of advance deposits to cover fees) available for the purposes specified in such section 507 [section 357 of this title] as in effect prior to the effective date shall also be available for the purposes specified in section 512(n) [subsection (n) of this section], including preparatory work or proceedings prior to that date.''

REGULATIONS

Section 2(c) of Pub. L. 103–396 provided that: ''Not later than 2 years after the date of the enactment of this Act [Oct. 22, 1994], the Secretary of Health and Human Services shall promulgate regulations to implement paragraphs (4)(A) and (5) of section 512(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(a)(4)(A), (5)] (as amended by subsection (a)).''

Section 103 of Pub. L. 100–670 provided that:

''(a) GENERAL RULE.—The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 512 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b], as amended by sections 101 through 103 of this title, within one year of the date of enactment of this Act [Nov. 16, 1988].

''(b) TRANSITION.—During the period beginning 60 days after the date of enactment of this Act [Nov. 16, 1988] and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new animal drug applications may be submitted in accordance with the provisions of section 314.55 and part 320 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 512(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(c)] before the date of enactment of this Act. If any such provision of section 314.55 or part 320 is inconsistent with the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (as amended by this title), the Secretary shall consider the application under the applicable requirements of section 512 (as so amended).''

DRUGS PRIMARILY MANUFACTURED USING BIOTECHNOLOGY

Section 106 of Pub. L. 100–670 provided that: ''Notwithstanding section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(b)(2)], the Secretary of Health and Human Services may not approve an abbreviated application submitted under such section for a new animal drug which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 351, 353, 360, 381, 382, 827 of this title; title 28 section 2201; title 35 sections 156, 271.

## § 360c. Classification of devices intended for human use

### (a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 360d and 360e of this title, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 360d and 360e of this title, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

**(b) Classification panels**

(1) For purposes of—

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f) of this section) into the classes established by subsection (a) of this section. For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before May 28, 1976, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

**(c) Classification panel organization and operation**

(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) of this section for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 360d or 360e of this title to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 360, 360i, or 360j(f) of this title.

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976.

**(d) Panel recommendation; publication; priorities**

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 360, 360i, or 360j(f) of this title shall not apply to the device. A regulation which makes a requirement of section 360, 360i, or 360j(f) of this title inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) of this section shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 360e(b)(1) of this title the Secretary may establish priorities which, in his discretion, shall be used in applying sections 360d and 360e of this title, as appropriate, to such devices.

**(e) Classification changes**

(1) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 360d of this title for such device.

(2) By regulation promulgated under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

**(f) Initial classification and reclassification of certain devices**

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II.

(2)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b) of this section. A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) of this section (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 360, 360i, and 360j(f) of this title) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B) of this section. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) of this section (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 360, 360i, and 360j(f) of this title) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(3) If a manufacturer reports to the Secretary under section 360(k) of this title that a device is substantially equivalent to another device—

(A) which the Secretary has classified as a class III device under subsection (b) of this section,

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 360e(b) of this title,

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 360(k) of this title a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 360(k) report is being made and which has not been submitted to the Secretary under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

**(g) Information**

Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this chapter, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this chapter applicable to the device.

**(h) Definitions**

For purposes of this section and sections 351, 360, 360d, 360e, 360f, 360i, and 360j of this title

(1) a reference to ''general controls'' is a reference to the controls authorized by or under

sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title,

(2) a reference to ''class I'', ''class II'', or ''class III'' is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1) of this section, and

(3) a reference to a ''panel under section 360c of this title'' is a reference to a panel established or authorized to be used under this section.

**(i) Substantial equivalence**

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(*l*) of this title, the term ''substantially equivalent'' or ''substantial equivalence'' means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term ''different technological characteristics'' means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(June 25, 1938, ch. 675, § 513, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 540; amended Nov. 28, 1990, Pub. L. 101–629, §§ 4(a), 5(a)–(c)(1), (3), 12(a), 18(a), 104 Stat. 4515, 4517, 4518, 4523, 4528; June 16, 1992, Pub. L. 102–300, § 6(e), 106 Stat. 240; Aug. 13, 1993, Pub. L. 103–80, § 3(s), 107 Stat. 778.)

REFERENCES IN TEXT

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (b)(1), is section 14 of Pub. L. 92–463, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

1993—Subsec. (b)(3). Pub. L. 103–80 substituted ''5703'' for ''5703(b)''.

1992—Subsec. (f)(3). Pub. L. 102–300 redesignated clauses (i) to (iii) as subpars. (A) to (C), respectively, and substituted ''the section 360(k) report'' for ''the 360(k) report'' in closing provisions.

1990—Subsec. (a)(1)(A)(ii). Pub. L. 101–629, § 5(a)(1), substituted ''or to establish special controls'' for ''or to establish a performance standard''.

Subsec. (a)(1)(B). Pub. L. 101–629, § 5(a)(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 360d of this title to provide reasonable assurance of its safety and effectiveness.''

Subsec. (a)(1)(C)(i). Pub. L. 101–629, § 5(a)(3), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: ''it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and''.

Subsec. (e). Pub. L. 101–629, § 5(b), designated existing provisions as par. (1), redesignated cls. (1) and (2) as (A) and (B), respectively, and added par. (2).

Subsec. (f). Pub. L. 101–629, § 5(c)(3), inserted ''and reclassification'' before ''of'' in heading.

Subsec. (f)(2)(A). Pub. L. 101–629, § 5(c)(1), substituted ''The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer'' for ''The manufacturer''.

Subsec. (f)(2)(B)(i). Pub. L. 101–629, § 18(a), substituted ''the Secretary may for good cause shown'' for ''the Secretary shall''.

Subsec. (f)(3). Pub. L. 101–629, § 4(a), added par. (3).

Subsec. (i). Pub. L. 101–629, § 12(a), added subsec. (i).

SHORT TITLE OF 1976 AMENDMENT

Pub. L. 94–295, § 1(a), May 28, 1976, 90 Stat. 539, provided that: ''This Act [enacting sections 360c to 360k, 379, and 379a of this title and section 3512 of Title 42, The Public Health and Welfare, and amending sections 321, 331, 334, 351, 352, 358, 360, 374, 379e, and 381 of this title and section 55 of Title 15, Commerce and Trade] may be cited as the 'Medical Device Amendments of 1976'.''

REGULATIONS

Section 12(b) of Pub. L. 101–629 provided that: ''Within 12 months of the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue regulations establishing the requirements of the summaries under section 513(i)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360c(i)(3)], as added by the amendment made by subsection (a).''

DAILY WEAR SOFT OR DAILY WEAR NONHYDROPHILIC PLASTIC CONTACT LENSES

Section 4(b)(3) of Pub. L. 101–629 provided that:

''(A) Notwithstanding section 520(*l*)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(*l*)(5)], the

Secretary of Health and Human Services shall not retain any daily wear soft or daily wear nonhydrophilic plastic contact lens in class III under such Act [this chapter] unless the Secretary finds that it meets the criteria set forth in section 513(a)(1)(C) of such Act [21 U.S.C. 360c(a)(1)(C)]. The finding and the grounds for the finding shall be published in the Federal Register. For any such lens, the Secretary shall make the determination respecting reclassification required in section 520(*l*)(5)(B) of such Act within 24 months of the date of the enactment of this paragraph [Nov. 28, 1990].

''(B) The Secretary of Health and Human Services may by notice published in the Federal Register extend the two-year period prescribed by subparagraph (A) for a lens for an additional period not to exceed one year.

''(C)(i) Before classifying a lens in class II pursuant to subparagraph (A), the Secretary of Health and Human Services shall pursuant to section 513(a)(1)(B) of such Act assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

''(ii) Prior to classifying a lens in class I pursuant to subparagraph (A), the Secretary shall assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

''(D) Notwithstanding section 520(*l*)(5) of such Act, if the Secretary of Health and Human Services has not made the finding and published the finding required by subparagraph (A) within 36 months of the date of the enactment of this subparagraph [Nov. 28, 1990], the Secretary shall issue an order placing the lens in class II.

''(E) Any person adversely affected by a final regulation under this paragraph revising the classification of a lens may challenge the revision of the classification of such lens only by filing a petition under section 513(e) for a classification change.''

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 360, 360d, 360e, 360g, 360j of this title.

## § 360d. Performance standards

### (a) Reasonable assurance of safe and effective performance; periodic evaluation

(1) The special controls required by section 360c(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 360c(e) of this title but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established under this section for a device—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title; and

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) The Secretary shall provide for periodic evaluation of performance standards established under this section to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under this section, the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies,

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

### (b) Establishment of a standard

(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 360c(e) of this title based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 360c of this title, either deny the request or give notice of an intent to initiate such change under section 360c(e) of this title.

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged;

and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(June 25, 1938, ch. 675, § 514, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 546; amended Oct. 8, 1976, Pub. L. 94–460, title III, § 304, 90 Stat. 1960; Nov. 28, 1990, Pub. L. 101–629, §§ 6(a), (b)(1), 18(b), 104 Stat. 4519, 4528; June 16, 1992, Pub. L. 102–300, § 6(g), 106 Stat. 241; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(1), 107 Stat. 779.)

AMENDMENTS

1993—Subsec. (b)(4)(B), (5)(A)(ii). Pub. L. 103–80 amended directory language of Pub. L. 101–619, § 18(b), identical to amendment by Pub. L. 102–300, § 6(g)(1). See 1992 and 1990 Amendment notes below.

1992—Subsec. (b)(4)(B), (5)(A)(ii). Pub. L. 102–300 made technical corrections to directory language of Pub. L. 101–629, § 18(b)(1), (2). See 1990 Amendment note below.

1990—Subsec. (a)(1). Pub. L. 101–629, § 6(a)(1), substituted ''The special controls required by section 360c(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.'' for ''The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for a class II device.''

Subsec. (b). Pub. L. 101–629, § 6(a)(2), (3), redesignated subsec. (g) as (b) and struck out former subsec. (b) which read as follows:

''(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

''(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title.''

Subsec. (b)(1), (2). Pub. L. 101–629, § 6(a)(4), amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

''(1)(A) After publication pursuant to subsection (c) of this section of a notice respecting a performance standard for a device, the Secretary shall either—

''(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary, (II) developed under subsection (c)(4) of this section, (III) accepted by the Secretary under subsection (d) of this section, or (IV) developed by him under subsection (f) of this section, or

''(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

''(B) If the Secretary issues under subparagraph (A)(ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

''(2) A notice of proposed rulemaking for the establishment of a performance standard for a device published under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device.''

Subsec. (b)(3)(A)(i). Pub. L. 101–629, § 6(b)(1)(A), substituted ''paragraph (1)'' for ''paragraph (2)''.

Subsec. (b)(4)(A). Pub. L. 101–629, § 6(b)(1)(B), substituted ''paragraphs (1), (2), and (3)(B)'' for ''paragraphs (2) and (3)(B)''.

Subsec. (b)(4)(B). Pub. L. 101–629, § 18(b)(1), as amended by Pub. L. 102–300, § 6(g)(1), (2), and Pub. L. 103–80, § 4(a)(1), struck out '', after affording all interested persons an opportunity for an informal hearing,'' after ''if he determines''.

Subsec. (b)(5)(A)(ii). Pub. L. 101–629, § 18(b)(2), as amended by Pub. L. 102–300, § 6(g)(1), (3), and Pub. L. 103–80, § 4(a)(1), substituted ''which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,'' for ''unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,''.

Subsecs. (c) to (f). Pub. L. 101–629, § 6(a)(2), struck out subsec. (c) relating to invitations for standards, subsec. (d) relating to acceptance of certain existing standards, subsec. (e) relating to acceptance of offers to develop standards, and subsec. (f) relating to development of standards by the Secretary after publication of notice inviting submissions or offers of standards.

Subsec. (g). Pub. L. 101–629, § 6(a)(3), redesignated subsec. (g) as (b).

1976—Subsec. (a). Pub. L. 94–460 redesignated pars. (4) and (5) as (3) and (4), respectively. Section as originally enacted contained no par. (3).

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 352, 360, 360c, 360e, 360g, 360j, 381 of this title.

## § 360e. Premarket approval

### (a) General requirement

A class III device—

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

**(b) Regulation to require premarket approval**

(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—

(i) the proposed regulation;

(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(B) If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title.

(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

**(c) Application for premarket approval**

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 360c of this title,

refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

**(d) Action on application for premarket approval**

(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the

receipt of an application under subsection (c) of this section (except as provided in section 360j(*l*)(3)(D)(ii) of this title or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) of this section unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title;

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 360d of this title compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section, and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g) of this section, of an order of the Secretary approving an application.

**(e) Withdrawal and temporary suspension of approval of application**

(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 360c of this title, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 360i(a) of this title, (ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title, or (iii) has not complied with the requirements of section 360 of this title;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 360j(f) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 360d of this title compli-

ance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

**(f) Product development protocol**

(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c) of this section, such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, he shall refer the proposed protocol to the appropriate panel under section 360c of this title for its recommendation respecting approval of the protocol.

(3) A proposed product development protocol for a device may be approved only if—

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c) of this section; and

(B) the Secretary determines that the proposed protocol provides—

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 360d of this title to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 360c of this title, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1) of this section.

(6)(A) The Secretary may, after providing the person who has an approved protocol and opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the

order. Such an order may be issued only if the Secretary finds—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

**(g) Review**

(1) Upon petition for review of—

(A) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) of this section revoking an approved protocol, under subsection (f)(6)(B) of this section declaring that an approved protocol has not been completed, or under subsection (f)(7) of this section revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of—

(i) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) of this section revoking an approved protocol, under subsection (f)(6)(B) of this section declaring that an approved protocol has not been completed, or under subsection (f)(7) of this section revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS–18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each

such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

**(h) Service of orders**

Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

**(i) Revision**

(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before December 1, 1995, the Secretary shall publish a regulation in the Federal Register for each device—

(A) which the Secretary has classified as a class III device, and

(B) for which no final regulation has been promulgated under subsection (b) of this section,

revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such regulation. No regulation requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed regulation.

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the regulation requiring a device to remain in class III, establish a schedule for the promulgation of a subsection (b) of this section regulation for each device which is subject to the regulation requiring the device to remain in class III.

(June 25, 1938, ch. 675, § 515, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 552; amended Nov. 28, 1990, Pub. L. 101–629, §§ 4(b)(1), 9(a), 18(c), 104 Stat. 4515, 4521, 4528; Aug. 13, 1993, Pub. L. 103–80, § 3(t), 107 Stat. 778.)

AMENDMENTS

1993—Subsec. (c)(2)(A). Pub. L. 103–80 struck out ''refer such application'' after ''own initiative''.

1990—Subsec. (c)(2). Pub. L. 101–629, § 18(c), substituted ''the Secretary—'' for ''the Secretary shall'' and added subpars. (A) and (B).

Subsec. (e). Pub. L. 101–629, § 9(a)(2), inserted ''and temporary suspension'' after ''Withdrawal'' in heading.

Subsec. (e)(3). Pub. L. 101–629, § 9(a)(1), added par. (3).

Subsec. (i). Pub. L. 101–629, § 4(b)(1), added subsec. (i).

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 353, 360, 360c, 360g, 360j, 381 of this title; title 35 section 156.

## § 360f. Banned devices

**(a) General rule**

Whenever the Secretary finds, on the basis of all available data and information, that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

**(b) Special effective date**

The Secretary may declare a proposed regulation under subsection (a) of this section to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

(June 25, 1938, ch. 675, § 516, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 560; amended Nov. 28, 1990, Pub. L. 101–629, § 18(d), 104 Stat. 4529.)

AMENDMENTS

1990—Subsec. (a). Pub. L. 101–629 struck out ''and after consultation with the appropriate panel or panels under section 360c of this title'' after ''data and information'' in introductory provisions and struck out at end ''The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360c, 360e, 360g, 360j, 381 of this title.

**§ 360g. Judicial review**

**(a) Petition; record**

Not later than thirty days after—

(1) the promulgation of a regulation under section 360c of this title classifying a device in class I or changing the classification of a device to class I or an order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device,

(2) the promulgation of a regulation under section 360d of this title establishing, amending, or revoking a performance standard for a device,

(3) the issuance of an order under section 360d(b)(2) or 360e(b)(2)(B) of this title denying a request for reclassification of a device,

(4) the promulgation of a regulation under paragraph (3) of section 360e(b) of this title requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 360e(g)(1) or 360e(g)(2)(C) of this title,

(5) the promulgation of a regulation under section 360f of this title (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

(6) the issuance of an order under section 360j(f)(2) of this title,

(7) an order under section 360j(g)(4) of this title disapproving an application for an exemption of a device for investigational use or an order under section 360j(g)(5) of this title withdrawing such an exemption for a device,

(8) an order pursuant to section 360c(i) of this title,

(9) a regulation under section 360e(i)(2) or 360j(*l*)(5)(B) of this title, or

(10) an order under section 360j(h)(4)(B) of this title,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28. For purposes of this section, the term ''record'' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

**(b) Additional data, views, and arguments**

If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

**(c) Standard for review**

Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) of this section and an order issued after the review provided by section 360e(g) of this title shall not be affirmed if it is found to be unsupported by sub-

stantial evidence on the record taken as a whole.

**(d) Finality of judgments**

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

**(e) Remedies**

The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

**(f) Statement of reasons**

To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k of this title each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

(June 25, 1938, ch. 675, § 517, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 560; amended Nov. 28, 1990, Pub. L. 101–629, § 13, 104 Stat. 4524; June 16, 1992, Pub. L. 102–300, § 6(f), 106 Stat. 240.)

AMENDMENTS

1992—Subsec. (a)(10). Pub. L. 102–300 substituted ''360j(h)(4)(B)'' for ''360j(c)(4)(B)''.

1990—Subsec. (a)(8) to (10). Pub. L. 101–629 added pars. (8) to (10).

## § 360h. Notification and other remedies

**(a) Notification**

If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

**(b) Repair, replacement, or refund**

(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,

(ii) there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture,

(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

(iv) the notification authorized by subsection (a) of this section would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph

(A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

(A) To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

(B) To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this chapter.

(C) To refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more—

(i) at the time of notification ordered under subsection (a) of this section, or

(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

**(c) Reimbursement**

An order issued under subsection (b) of this section with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

**(d) Effect on other liability**

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

**(e) Recall authority**

(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)—

(A) to immediately cease distribution of such device, and

(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) An amended order under subparagraph (A)—

(i) shall—

(I) not include recall of a device from individuals, and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 375(b) of this title.

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c) of this section.

(June 25, 1938, ch. 675, § 518, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 562; amended Nov. 28, 1990, Pub. L. 101–629, § 8, 104 Stat. 4520; June 16, 1992, Pub. L. 102–300, § 4, 106 Stat. 239.)

AMENDMENTS

1992—Subsec. (b)(1)(A)(ii). Pub. L. 102–300 substituted ''or'' for ''and'' after ''properly designed'' and ''time of its design''.

1990—Subsec. (e). Pub. L. 101–629 added subsec. (e).

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360c, 360g, 360j of this title.

**§ 360i. Records and reports on devices**

**(a) General rule**

Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(A) may have caused or contributed to a death or serious injury, or

(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

(2) shall define the term ''serious injury'' to mean an injury that—

(A) is life threatening,

(B) results in permanent impairment of a body function or permanent damage to a body structure, or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(4) shall not impose requirements unduly burdensome to a device manufacturer, importer, or distributor taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

(7) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this chapter;

(8) may not require a manufacturer, importer, or distributor of a class I device to—

(A) maintain for such a device records respecting information not in the possession of the manufacturer, importer, or distributor, or

(B) to submit for such a device to the Secretary any report or information—

(i) not in the possession of the manufacturer, importer, or distributor, or

(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded; and

(9) shall require distributors who submit such reports to submit copies of the reports to the manufacturer of the device for which the report was made.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (7) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

**(b) User reports**

(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of—

(i) information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, or

(ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on a semi-annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 and July 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include—

(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

The Secretary may by regulation alter the frequency and timing of reports required by this subparagraph.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

(A) an action brought to enforce section 331(q) of this title,

(B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1), or

(C) a disclosure required under subsection (a) of this section.

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

(3) No report made under paragraph (1) by—

(A) a device user facility,

(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

(C) a physician who is not required to make such a report,

shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a) of this section.

(5) For purposes of this subsection:

(A) The term ''device user facility'' means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by regulation include an outpatient diagnostic facility which is not a physician's office in such term.

(B) The terms ''serious illness'' and ''serious injury'' mean illness or injury, respectively, that—

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

**(c) Persons exempt**

Subsection (a) of this section shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 360j(g) of this title); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) of this section upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

**(d) Certification**

Each manufacturer, importer, and distributor required to make reports under subsection (a) of this section shall submit to the Secretary annually a statement certifying that—

(1) the manufacturer, importer, or distributor did file a certain number of such reports, or

(2) the manufacturer, importer, or distributor did not file any report under subsection (a) of this section.

**(e) Device tracking**

Every person who registers under section 360 of this title and is engaged in the manufacture of—

(1) a device the failure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a life sustaining or life supporting device used outside a device user facility, or

(2) any other device which the Secretary may designate,

shall adopt a method of device tracking.

**(f) Reports of removals and corrections**

(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer, importer, or distributor of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer, importer, or distributor if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this chapter caused by the device which may present a risk to health.

A manufacturer, importer, or distributor of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a) of this section.

(3) For purposes of paragraphs (1) and (2), the terms ''correction'' and ''removal'' do not include routine servicing.

(June 25, 1938, ch. 675, § 519, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 564; amended Nov. 28, 1990, Pub. L. 101–629, §§ 2(a), 3(a)(1), (b)(1), 7, 104 Stat. 4511, 4513, 4514, 4520; June 16, 1992, Pub. L. 102–300, § 5(a), 106 Stat. 239; Aug. 13, 1993, Pub. L. 103–80, § 3(u), 107 Stat. 778.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–80 substituted ''paragraph (7)'' for ''paragraph (4)'' in last sentence.

1992—Subsec. (a). Pub. L. 102–300, § 5(a)(1), added pars. (1) to (3) and redesignated former pars. (1) to (6) as (4) to (9), respectively.

Subsec. (b)(1)(A). Pub. L. 102–300, § 5(a)(2)(A), substituted ''a device has or may have'' for ''there is a probability that a device has''.

Subsec. (b)(1)(B). Pub. L. 102–300, § 5(a)(2)(A), (B), substituted ''a device has or may have'' for ''there is a probability that a device has'', designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (b)(5)(B)(iii). Pub. L. 102–300, § 5(a)(2)(C), struck out ''immediate'' before ''medical''.

1990—Subsec. (a)(6). Pub. L. 101–629, § 3(a)(1), added par. (6).

Subsecs. (b), (c). Pub. L. 101–629, § 2(a), added subsec. (b) and redesignated former subsec. (b) as (c).

Subsecs. (d), (e). Pub. L. 101–629, § 3(b)(1), added subsecs. (d) and (e).

Subsec. (f). Pub. L. 101–629, § 7, added subsec. (f).

EFFECTIVE DATE OF 1992 AMENDMENT

Section 2(b) of Pub. L. 102–300 provided that: ''The amendments made by subsection (a) [amending sections 3(b)(3) and 3(c) of Pub. L. 101–629, set out as notes below] shall take effect as of May 27, 1992 and any rule to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(e)] proposed under section 3(c)(2) of the Safe Medical Devices Act of 1990 [Pub. L. 101–629, set out as a note below] shall revert to its proposed status as of such date.''

Section 5(b) of Pub. L. 102–300 provided that: ''The amendments made by subsection (a) [amending this section] shall take effect—

''(1) 1 year after the date of the enactment of this Act [June 16, 1992]; or

''(2) on the effective date of regulations of the Secretary to implement such amendments,

whichever occurs first.''

EFFECTIVE DATE OF 1990 AMENDMENT

Section 2(c) of Pub. L. 101–629 provided that: ''Section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a), shall take effect—

''(1) upon the effective date of regulations promulgated under subsection (b) [set out below], or

''(2) upon the expiration of 12 months from the date of the enactment of this Act [Nov. 28, 1990],

whichever occurs first.''

Section 3(a)(2) of Pub. L. 101–629 provided that: ''Section 519(a)(6) [21 U.S.C. 360i(a)(6)], as added by the amendment made by paragraph (1), shall take effect upon the effective date of final regulations under subsection (c) [set out below].''

Section 3(b)(3) of Pub. L. 101–629, as amended by Pub. L. 102–300, § 2(a)(1), June 16, 1992, 106 Stat. 238, provided that: ''Section 519(e) [21 U.S.C. 360i(e)], as added by the amendment made by paragraph (1), shall take effect upon the expiration of 9 months after the issuance of final regulations under subsection (c) [set out below].''

[For effective date of amendment by Pub. L. 102–300, see section 2(b) of Pub. L. 102–300, set out above as an Effective Date of 1992 Amendment note.]

REGULATIONS

Section 2(b) of Pub. L. 101–629 provided that: ''The Secretary of Health and Human Services shall promulgate regulations to implement section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a) (including a definition of the summary required by paragraph (1)(C) of such section) not later than 12 months after the date of enactment of this Act [Nov. 28, 1990]. In promulgating the regulations, the Secretary shall minimize the administrative burdens on device user facilities consistent with the need to assure adequate information.''

Section 3(c) of Pub. L. 101–629, as amended by Pub. L. 102–300, § 2(a)(2), (3), June 16, 1992, 106 Stat. 238, provided that:

''(1)(A) Not later than 9 months after the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue proposed regulations—

''(i) to require distributors of devices to establish and maintain records and to make reports (including reports required by part 803 of title 21 of the Code of Federal Regulations) under section 519(a)(6) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(a)(6)], and

''(ii) to implement section 519(e) of such Act.

The Secretary may exempt from regulations described in clause (i) classes of distributors of class I and class II devices from whom reports are not necessary for the protection of the public health.

''(B) Regulations under subparagraph (A) shall—

''(i) require appropriate methods for maintenance of records to ensure that patients who receive devices can be provided the notification required by such Act [this chapter],

''(ii) require that manufacturers adopt effective methods of tracking devices,

''(iii) take into account the position of distributors in the device distribution process, and

''(iv) include such other requirements as the Secretary deems necessary for the adoption of an effective user tracking program under section 519(e) of such Act.

''(2) Not later than 18 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement sections [sic] 519(a)(6) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations upon the expiration of such 18 months, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of sections [sic] 519(a)(6) of such Act is essential to protect the health of patients who use such devices. Consequently, in such event, the proposed regulations issued under paragraph (1) shall become final regulations as of the expiration of such 18 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.

''(3) Not later than November 28, 1992, the Secretary shall issue final regulations to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations by November 28, 1992, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of section 519(e) of such Act is essential to protect the health of patients who use devices. In such event, the proposed regulations issued under paragraph (1) shall become the issued final regulations on November 29, 1992. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.''

[For effective date of amendment by Pub. L. 102–300, see section 2(b) of Pub. L. 102–300, set out above as an Effective Date of 1992 Amendment note.]

INFORMATION CONCERNING REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(d) of Pub. L. 101–629 directed Secretary of Health and Human Services, during the 18-month period beginning on Nov. 28, 1990, to inform device user facilities (as defined in 21 U.S.C. 360i(b)(5)(A)) and man-

ufacturers and distributors of devices respecting the requirements of 21 U.S.C. 360i(b), and, to the extent practicable, provide persons subject to such requirements assistance in the form of publications regarding such requirements.

STUDY OF REPORTING REQUIREMENTS; COMPLIANCE BY DEVICE USER FACILITIES; ACTIONS BY MANUFACTURERS; COST EFFECTIVENESS; RECOMMENDATIONS

Section 2(e) of Pub. L. 101–629 directed Comptroller General of the United States, not more than 36 months after Nov. 28, 1990, to conduct a study of compliance by device user facilities with the requirements of 21 U.S.C. 360i(b), actions taken by manufacturers of devices in response to reports made to them, cost effectiveness of such requirements and their implementation, and any recommendations for improvements to such requirements, with Comptroller General to complete the study and submit a report on the study not later than 45 months from Nov. 28, 1990, to appropriate committees of Congress.

REPORT TO CONGRESS ON REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(f) of Pub. L. 101–629 directed Secretary of Health and Human Services, not later than 36 months after Nov. 28, 1990, to prepare and submit to appropriate committees of Congress a report containing an evaluation of the requirements of 21 U.S.C. 360i(b), consisting of an evaluation of the safety benefits of the requirements, the burdens placed on the Food and Drug Administration and on device user facilities by the requirements, and the cost-effectiveness of the requirements and recommendations for legislative reform.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 352, 360c, 360e, 360g, 360j, 374 of this title.

## § 360j. General provisions respecting control of devices intended for human use

### (a) General rule

Any requirement authorized by or under section 351, 352, 360, or 360i of this title applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 360c, 360d, or 360e of this title or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a requirement imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

### (b) Custom devices

Sections 360d and 360e of this title do not apply to any device which, in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 360e of this title if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

(A)(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

(ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

### (c) Trade secrets

Any information reported to or otherwise obtained by the Secretary or his representative under section 360c, 360d, 360e, 360f, 360h, 360i, or 374 of this title or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 360d of this title for a device reclassified from class III to class II, except (1) in accordance with subsection (h) of this section, and (2) that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter (other than section 360c or 360d of this title).

### (d) Notices and findings

Each notice of proposed rulemaking under section 360c, 360d, 360e, 360f, 360h, or 360i of this title, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

### (e) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under

subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

**(f) Good manufacturing practice requirements**

(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated, and

(ii) afford opportunity for an oral hearing.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter,

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

(iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve—

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this chapter.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are

so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

**(g) Exemption for devices for investigational use**

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i, or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if—

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 360f of this title) shall be deemed approved on the

thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

**(h) Release of information respecting safety and effectiveness**

(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

(A) an order under section 360e(d)(1)(A) of this title approving an application for premarket approval for the device or denying approval of such an application or an order under section 360e(e) of this title withdrawing approval of such an application for the device,

(B) an order under section 360e(f)(6)(A) of this title revoking an approved protocol for the device, an order under section 360e(f)(6)(B) of this title declaring a protocol for the device completed or not completed, or an order under section 360e(f)(7) of this title revoking the approval of the device, or

(C) an order approving an application under subsection (g) of this section for an exemption for the device from section 360f of this title or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) The Secretary shall promulgate regulations under which each advisory committee established under section 360e(g)(2)(B) of this title shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 360e(g)(2)(A) of this title. A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order.

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this chapter by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 360e(c) of this title, including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a device shall be available 1 year after the original application for the fourth device of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 360e of this title, establishing a performance standard under section 360d of this title, and reclassifying devices under subsections (e) and (f) of section 360c of this title, and subsection (*l*)(2) of this section. The Secretary shall deem devices that incorporate the same technologies, have the same principles of operation, and are intended for the same use or uses to be within a kind of device.

(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish an order in the Federal Register identifying the four devices of a kind that have been approved under section 360e of this title and the date on which the data contained in premarket approval applications for the devices will be available to the Secretary for use, as described in subparagraph (A).

(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).

(D)(i) This paragraph shall become effective—

(I) on November 15, 1990, for devices for which four devices of a kind were approved on or before December 31, 1987, and

(II) on November 15, 1991, for devices not described in subclause (I).

(ii) For each device described in clause (i)(I), the Secretary shall publish a notice in the Federal Register setting forth the date, which shall be not earlier than 1 year after the date of the notice, that data identified in subparagraph (A) shall be available for the use of the Secretary.

(E)(i) Except as provided in clause (ii), the approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 360e of this title and permitting the applicant to commercially distribute the device.

(ii) For each device described in subparagraph (D)(i)(II) for which the original application for a fourth device of a kind is approved by the Secretary before November 1, 1991, the approval date of the fourth device of a kind shall be deemed to be November 15, 1991.

(F) Any challenge to an order under subparagraph (B) shall be made not later than 30 days after the date of the Federal Register notice referred to in such subparagraph.

**(i) Proceedings of advisory panels and committees**

Each panel under section 360c of this title and each advisory committee established under section 360d(b)(5)(B) or 360e(g) of this title or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

**(j) Traceability**

Except as provided in section 360i(e) of this title, no regulation under this chapter may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

**(k) Research and development**

The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to section 3324(a) and (b) of title 31 and section 5 of title 41.

**(*l*) Transitional provisions for devices considered as new drugs or antibiotic drugs**

(1) Any device intended for human use—

(A) for which on May 28, 1976 (hereinafter in this subsection referred to as the ''enactment date'') an approval of an application submitted under section 355(b) of this title was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 355 of this title; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 332, 333, or 334 of this title for an alleged violation of a provision of section 331 of this title which enforces a requirement of section 355 of this title or for an alleged violation of section 355(a) of this title,

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under section 360c of this title, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 360c(a)(1)(A) of this title or 360c(a)(1)(B) of this title, of the device in class I or class II.

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 360e of this title, and

(ii) the requirements applicable to such device before the enactment date under section 355 of this title shall continue to apply to such device until changed by the Secretary as authorized by this chapter.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 360e of this title on the enactment date. The period in which the Secretary shall act on such application in accordance with section 360e(d)(1) of this title shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 360e(d)(1)(B)(i) of this title) less the number of days in the period beginning on the date an application for such device was filed under section 355 of this title and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g) of this section, to have in effect an approved application under section 360e of this title.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g) of this section, to have in effect an approved application under section 360e of this title.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 360e of this title.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 360e of this title for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 360e(d)(1)(B) of this title, and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 360e of this title except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 355 of this title, and which is in class III—

(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 360e of this title unless exempt under subsection (g) of this section, and

(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(4) Any device intended for human use which on the enactment date was subject to the requirements of section 357 of this title shall be subject to such requirements as follows:

(A) In the case of such a device which is classified into class I, such requirements shall apply to such device until the effective date of the regulation classifying the device into such class.

(B) In the case of such a device which is classified into class II, such requirements shall apply to such device until the effective date of a performance standard applicable to the device under section 360d of this title.

(C) In the case of such a device which is classified into class III, such requirements shall apply to such device until the date on which the device is required to have in effect an approved application under section 360e of this title.

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

**(m) Humanitarian device exemption**

(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 360d and 360e of this title for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemp-

tion, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

(3) No person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to supervise clinical testing of devices in the facilities, and

(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A).

(5) An exemption under paragraph (2) shall be for a term of 18 months and may only be initially granted in the 5-year period beginning on the date regulations under paragraph (6) take effect. The Secretary may extend such an exemption for a period of 18 months if the Secretary is able to make the findings set forth in paragraph (2) and if the applicant supplies information demonstrating compliance with paragraph (3). An exemption may be extended more than once and may be extended after the expiration of such 5-year period.

(6) Within one year of November 28, 1990, the Secretary shall issue regulations to implement this subsection.

(June 25, 1938, ch. 675, § 520, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 565; amended Nov. 28, 1990, Pub. L. 101–629, §§ 3(b)(2), 4(b)(2), 5(c)(2), 6(b)(2), 11, 14(a), 18(e), (f), 104 Stat. 4514, 4516, 4518, 4519, 4522, 4524, 4529; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(10), 106 Stat. 4499.)

REFERENCES IN TEXT

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (f)(3), is section 14 of Pub. L. 92–463, which is set out in the Appendix to Title 5, Government Organization and Employees.

CODIFICATION

In subsec. (k), ''section 3324(a) and (b) of title 31'' substituted for reference to section 3648 of the Revised Statutes (31 U.S.C. 529) on authority of Pub. L. 97–258, § 4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

AMENDMENTS

1992—Subsec. (g)(2)(A). Pub. L. 102–571 substituted ''379e'' for ''376''.

1990—Subsec. (c). Pub. L. 101–629, § 11(1), substituted ''from class III to class II or class I'' for ''under section 360c of this title from class III to class II'' and inserted ''(1) in accordance with subsection (h) of this section, and (2)'' after ''except''.

Subsec. (f)(1)(A). Pub. L. 101–629, § 18(e), inserted ''preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device),'' after ''manufacture,''.

Subsec. (h)(3). Pub. L. 101–629, § 11(2)(A), substituted ''Except as provided in paragraph (4), any'' for ''Any''.

Subsec. (h)(4). Pub. L. 101–629, § 11(2)(B), added par. (4).

Subsec. (i). Pub. L. 101–629, § 6(b)(2), substituted ''section 360d(b)(5)(B)'' for ''section 360d(g)(5)(B)''.

Subsec. (j). Pub. L. 101–629, § 3(b)(2), substituted ''Except as provided in section 360i(e) of this title, no'' for ''No''.

Subsec. (*l*)(2). Pub. L. 101–629, § 18(f), struck out ''and after affording the petitioner an opportunity for an informal hearing'' after ''under this paragraph''.

Pub. L. 101–629, § 5(c)(2), substituted ''The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer'' for ''The manufacturer''.

Subsec. (*l*)(5). Pub. L. 101–629, § 4(b)(2), added par. (5).

Subsec. (m). Pub. L. 101–629, § 14(a), added subsec. (m).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 14(b) of Pub. L. 101–629 provided that: ''Subsection (m) of section 520 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(m)], as added by the amendment made by subsection (a), shall take effect on the effective date of the regulations issued by the Secretary under paragraph (6) of such subsection.''

REPORT ON HUMANITARIAN DEVICE EXEMPTIONS

Section 14(c) of Pub. L. 101–629 directed Secretary of Health and Human Services, within 4 years after issuance of regulations under 21 U.S.C. 360j(m)(6), to report to Congress on types of devices exempted, an evaluation of effects of such section, and a recommendation on extension of the section.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 351, 352, 353, 360c, 360d, 360e, 360g, 360i, 374, 381, 383 of this title.

## § 360k. State and local requirements respecting devices

### (a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

### (b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, ch. 675, § 521, as added May 28, 1976, Pub. L. 94–295, § 2, 90 Stat. 574.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360g of this title.

### § 360*l*. Postmarket surveillance

#### (a) In general

##### (1) Required surveillance

The Secretary shall require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that—

(A) is a permanent implant the failure of which may cause serious, adverse health consequences or death,

(B) is intended for a use in supporting or sustaining human life, or

(C) potentially presents a serious risk to human health.

##### (2) Discretionary surveillance

The Secretary may require a manufacturer to conduct postmarket surveillance for a device of the manufacturer if the Secretary determines that postmarket surveillance of the device is necessary to protect the public health or to provide safety or effectiveness data for the device.

#### (b) Surveillance approval

Each manufacturer required to conduct a surveillance of a device under subsection (a)(1) of this section shall, within 30 days of the first introduction or delivery for introduction of such device into interstate commerce, submit, for the approval of the Secretary, a protocol for the required surveillance. Each manufacturer required to conduct a surveillance of a device under subsection (a)(2) of this section shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.

(June 25, 1938, ch. 675, § 522, as added Nov. 28, 1990, Pub. L. 101–629, § 10, 104 Stat. 4521; amended June 16, 1992, Pub. L. 102–300, § 3(b), 106 Stat. 239.)

AMENDMENTS

1992—Subsec. (b). Pub. L. 102–300 substituted ''(a)(1)'' for ''(a)'', inserted comma after ''commerce'', and inserted after first sentence ''Each manufacturer required to conduct a surveillance of a device under subsection (a)(2) of this section shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352 of this title.

## PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

PART REFERRED TO IN OTHER SECTIONS

This part is referred to in title 42 section 236.

### § 360aa. Recommendations for investigations of drugs for rare diseases or conditions

#### (a) Request by sponsor; response by Secretary

The sponsor of a drug for a disease or condition which is rare in the States may request the Secretary to provide written recommendations for the non-clinical and clinical investigations which must be conducted with the drug before—

(1) it may be approved for such disease or condition under section 355 of this title,

(2) if the drug is an antibiotic, it may be certified for such disease or condition under section 357 of this title, or

(3) if the drug is a biological product, it may be licensed for such disease or condition under section 262 of title 42.

If the Secretary has reason to believe that a drug for which a request is made under this section is a drug for a disease or condition which is rare in the States, the Secretary shall provide the person making the request written recommendations for the non-clinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval of such drug for such disease or condition under section 355 of this title, certification of such drug for such disease or condition under section 357 of this title, or licensing of such drug for such disease or condition under section 262 of title 42.

#### (b) Regulations

The Secretary shall by regulation promulgate procedures for the implementation of subsection (a) of this section.

(June 25, 1938, ch. 675, § 525, as added Jan. 4, 1983, Pub. L. 97–414, § 2(a), 96 Stat. 2049; amended Aug. 15, 1985, Pub. L. 99–91, § 3(a)(1), 99 Stat. 387.)

AMENDMENTS

1985—Subsec. (a). Pub. L. 99–91 struck out ''or'' at end of par. (1), inserted par. (2), redesignated former par. (2) as (3) and struck out ''before'' after ''product,'', and in last sentence inserted provisions relating to certification of such drug for disease or condition under section 357 of this title and substituted ''licensing of such drug for such disease or condition under section 262 of title 42'' for ''licensing under section 262 of title 42 for such disease or condition''.

EFFECTIVE DATE OF 1985 AMENDMENT

Section 8 of Pub. L. 99–91 provided that:

''(a) GENERAL RULE.—Except as provided in subsection (b), this Act and the amendments made by this Act [amending this section, sections 360bb, 360cc, and 360ee of this title, and sections 295g–1 and 6022 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under section 301 of this title and section 236 of Title 42] shall take effect October 1, 1985.

''(b) EXCEPTION.—The amendments made by sections 2, 3, and 6(a) [amending this section and sections 360bb and 360cc of this title] shall take effect on the date of the enactment of this Act [Aug. 15, 1985]. The amendment made by section 6(b) [amending section 6022 of Title 42] shall take effect October 19, 1984. The amendments made by section 7 [amending section 295g–1 of Title 42] shall take effect October 1, 1984 and shall cease to be in effect after September 30, 1985.''

STUDY

Pub. L. 100–290, § 3(d), Apr. 18, 1988, 102 Stat. 91, directed Secretary of Health and Human Services to conduct a study to determine whether the application of subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360aa et seq. (relating to drugs for rare diseases and conditions), and 26 U.S.C. 28 (relating to tax credit) to medical devices or medical foods for rare diseases or conditions or to both was needed to encourage development of such devices and foods and report results of the study to Congress not later than one year after Apr. 18, 1988.

CONGRESSIONAL FINDINGS

Section 1(b) of Pub. L. 97–414 provided that: ''The Congress finds that—

''(1) there are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which affect such small numbers of individuals residing in the United States that the diseases and conditions are considered rare in the United States;

''(2) adequate drugs for many of such diseases and conditions have not been developed;

''(3) drugs for these diseases and conditions are commonly referred to as 'orphan drugs';

''(4) because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss;

''(5) there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs; and

''(6) it is in the public interest to provide such changes and incentives for the development of orphan drugs.''

## § 360bb. Designation of drugs for rare diseases or conditions

### (a) Request by sponsor; preconditions; "rare disease or condition" defined

(1) The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition. A request for designation of a drug shall be made before the submission of an application under section 355(b) of this title for the drug, the submission of an application for certification of the drug under section 357 of this title, or the submission of an application for licensing of the drug under section 262 of title 42. If the Secretary finds that a drug for which a request is submitted under this subsection is being or will be investigated for a rare disease or condition and—

(A) if an application for such drug is approved under section 355 of this title,

(B) if a certification for such drug is issued under section 357 of this title, or

(C) if a license for such drug is issued under section 262 of title 42,

the approval, certification, or license would be for use for such disease or condition, the Secretary shall designate the drug as a drug for such disease or condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) of this section respecting the designation of the drug.

(2) For purposes of paragraph (1), the term ''rare disease or condition'' means any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

### (b) Notification of discontinuance of drug or application as condition

A designation of a drug under subsection (a) of this section shall be subject to the condition that—

(1) if an application was approved for the drug under section 355(b) of this title, a certificate was issued for the drug under section 357 of this title, or a license was issued for the drug under section 262 of title 42, the manufacturer of the drug will notify the Secretary of any discontinuance of the production of the drug at least one year before discontinuance, and

(2) if an application has not been approved for the drug under section 355(b) of this title, a certificate has not been issued for the drug under section 357 of this title, or a license has not been issued for the drug under section 262 of title 42 and if preclinical investigations or investigations under section 355(i) of this title are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 355(b) of this title, approval of an application for certification under section 357 of this title, or approval of a license under section 262 of title 42.

### (c) Notice to public

Notice respecting the designation of a drug under subsection (a) of this section shall be made available to the public.

### (d) Regulations

The Secretary shall by regulation promulgate procedures for the implementation of subsection (a) of this section.

(June 25, 1938, ch. 675, § 526, as added Jan. 4, 1983, Pub. L. 97–414, § 2(a), 96 Stat. 2050; amended Oct.

30, 1984, Pub. L. 98–551, § 4(a), 98 Stat. 2817; Aug. 15, 1985, Pub. L. 99–91, § 3(a)(2), 99 Stat. 387; Apr. 18, 1988, Pub. L. 100–290, § 2, 102 Stat. 90.)

AMENDMENTS

1988—Subsec. (a)(1). Pub. L. 100–290, § 2(a), inserted after first sentence "A request for designation of a drug shall be made before the submission of an application under section 355(b) of this title for the drug, the submission of an application for certification of the drug under section 357 of this title, or the submission of an application for licensing of the drug under section 262 of title 42."

Subsecs. (b) to (d). Pub. L. 100–290, § 2(b), added subsec. (b) and redesignated former subsecs. (b) and (c) as (c) and (d), respectively.

1985—Subsec. (a)(1). Pub. L. 99–91 struck out "or" at end of subpar. (A), struck out subpar. (B) and substituted subpars. (B) and (C), and inserted ", certification," after "approval".

1984—Subsec. (a)(2). Pub. L. 98–551 substituted "which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which" for "which occurs so infrequently in the United States that".

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–91 effective Aug. 15, 1985, see section 8(b) of Pub. L. 99–91, set out as a note under section 360aa of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360cc, 360dd, 360ee of this title; title 26 section 28; title 42 section 236.

## § 360cc. Protection for drugs for rare diseases or conditions

### (a) Exclusive approval, certification, or license

Except as provided in subsection (b) of this section, if the Secretary—

(1) approves an application filed pursuant to section 355 of this title,

(2) issues a certification under section 357 of this title, or

(3) issues a license under section 262 of title 42

for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application under section 355 of this title, issue another certification under section 357 of this title, or issue another license under section 262 of title 42 for such drug for such disease or condition for a person who is not the holder of such approved application, of such certification, or of such license until the expiration of seven years from the date of the approval of the approved application, the issuance of the certification, or the issuance of the license. Section 355(c)(2) of this title does not apply to the refusal to approve an application under the preceding sentence.

### (b) Exceptions

If an application filed pursuant to section 355 of this title is approved for a drug designated under section 360bb of this title for a rare disease or condition, if a certification is issued under section 357 of this title for such a drug, or if a license is issued under section 262 of title 42 for such a drug, the Secretary may, during the seven-year period beginning on the date of the application approval, of the issuance of the certification under section 357 of this title, or of the issuance of the license, approve another application under section 355 of this title, issue another certification under section 357 of this title, or issue a license under section 262 of title 42, for such drug for such disease or condition for a person who is not the holder of such approved application, of such certification, or of such license if—

(1) the Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application, of such certification, or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications, issuance of other certifications, or the issuance of other licenses before the expiration of such seven-year period.

(June 25, 1938, ch. 675, § 527, as added Jan. 4, 1983, Pub. L. 97–414, § 2(a), 96 Stat. 2050; amended Sept. 24, 1984, Pub. L. 98–417, title I, § 102(b)(6), 98 Stat. 1593; Aug. 15, 1985, Pub. L. 99–91, §§ 2, 3(a)(3), 99 Stat. 387, 388; Aug. 13, 1993, Pub. L. 103–80, § 3(v), 107 Stat. 778.)

AMENDMENTS

1993—Subsec. (b). Pub. L. 103–80 struck out extraneous comma before "or issue a license under section 262" in introductory provisions and substituted "the" for "The" at beginning of par. (1).

1985—Pub. L. 99–91, § 2(3), struck out "unpatented" before "drugs" in section catchline.

Subsec. (a). Pub. L. 99–91, §§ 2(1), 3(a)(3)(A)–(D), struck out "or" at end of par. (1), added par. (2), redesignated former par. (2) as (3), struck out "and for which a United States Letter of Patent may not be issued" after "rare disease or condition", inserted in first sentence ", issue another certification under section 357 of this title," after "section 355 of this title" the second time it appeared, inserted ", of such certification," after "holder of such approved application", and inserted ", the issuance of the certification," after "approval of the approved application".

Subsec. (b). Pub. L. 99–91, §§ 2(2), 3(a)(3)(E)–(K), struck out "and if a United States Letter of Patent may not be issued for the drug" after "such a drug", substituted ", if a certification is issued under section 357 of this title for such a drug, or if a license" for "or a license", inserted ", of the issuance of the certification under section 357 of this title," after "application approval", struck out ", if the drug is a biological product," before "issue a license", inserted ", issue another certification under section 357 of this title," after "section 355 of this title", inserted ", of such certification," after "holder of such approved application", inserted ", of such certification," after "application" in par. (1), and inserted ", issuance of other certifications," after "other applications" in par. (2).

1984—Subsecs. (a), (b). Pub. L. 98–417 substituted "section 355" for "section 355(b)" wherever appearing.

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–91 effective Aug. 15, 1985, see section 8(b) of Pub. L. 99–91, set out as a note under section 360aa of this title.

## § 360dd. Open protocols for investigations of drugs for rare diseases or conditions

If a drug is designated under section 360bb of this title as a drug for a rare disease or condi-

tion and if notice of a claimed exemption under section 355(i) of this title or regulations issued thereunder is filed for such drug, the Secretary shall encourage the sponsor of such drug to design protocols for clinical investigations of the drug which may be conducted under the exemption to permit the addition to the investigations of persons with the disease or condition who need the drug to treat the disease or condition and who cannot be satisfactorily treated by available alternative drugs.

(June 25, 1938, ch. 675, § 528, as added Jan. 4, 1983, Pub. L. 97–414, § 2(a), 96 Stat. 2051.)

### § 360ee. Grants and contracts for development of drugs for rare diseases and conditions

**(a) Authority of Secretary**

The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the costs of qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions.

**(b) Definitions**

For purposes of subsection (a) of this section:

(1) The term ''qualified testing'' means—

(A) human clinical testing—

(i) which is carried out under an exemption for a drug for a rare disease or condition under section 355(i) of this title (or regulations issued under such section); and

(ii) which occurs after the date such drug is designated under section 360bb of this title and before the date on which an application with respect to such drug is submitted under section 355(b) or 357 of this title or under section 262 of title 42; and

(B) preclinical testing involving a drug for a rare disease or condition which occurs after the date such drug is designated under section 360bb of this title and before the date on which an application with respect to such drug is submitted under section 355(b) or 357 of this title or under section 262 of title 42.

(2) The term ''rare disease or condition'' means (1) in the case of a drug, any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug, (2) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance under subsection (a) of this section, and (3) in the case of a medical food, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such disease or condition will be developed without assistance under subsection (a) of this section. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 360bb of this title is made.

(3) The term ''medical food'' means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

**(c) Authorization of appropriations**

For grants and contracts under subsection (a) of this section there are authorized to be appropriated $10,000,000 for fiscal year 1988, $12,000,000 for fiscal year 1989,[1] $14,000,000 for fiscal year 1990.

(Pub. L. 97–414, § 5, Jan. 4, 1983, 96 Stat. 2056; Pub. L. 98–551, § 4(b), Oct. 30, 1984, 98 Stat. 2817; Pub. L. 99–91, § 5, Aug. 15, 1985, 99 Stat. 391; Pub. L. 100–290, § 3(a)–(c), Apr. 18, 1988, 102 Stat. 90, 91.)

CODIFICATION

Section was enacted as part of the Orphan Drug Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

AMENDMENTS

1988—Subsec. (a). Pub. L. 100–290, § 3(a)(1), (b)(1), inserted ''(1)'' after ''assist in'' and added cls. (2) and (3).

Subsec. (b)(2). Pub. L. 100–290, § 3(a)(2), (b)(2), inserted ''(1) in the case of a drug,'' after ''means'', added cls. (2) and (3), and substituted ''under section 360bb of this title'' for ''under this subsection'' in last sentence.

Subsec. (b)(3). Pub. L. 100–290, § 3(b)(3), added par. (3).

Subsec. (c). Pub. L. 100–290, § 3(c), amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: ''For grants and contracts under subsection (a) of this section there are authorized to be appropriated $4,000,000 for fiscal year 1986, $4,000,000 for fiscal year 1987, and $4,000,000 for fiscal year 1988.''

1985—Subsec. (a). Pub. L. 99–91, § 5(a)(1), struck out ''clinical'' before ''testing''.

Subsec. (b)(1). Pub. L. 99–91, § 5(a)(2), substituted provisions defining ''qualified testing'' for provisions defining ''qualified clinical testing''.

Subsec. (c). Pub. L. 99–91, § 5(b), substituted provisions authorizing appropriations for fiscal years 1986 to 1988, for provisions authorizing appropriations for fiscal years 1983 and the two succeeding fiscal years.

1984—Subsec. (b)(2). Pub. L. 98–551 substituted ''which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which'' for ''which occurs so infrequently in the United States that''.

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–91 effective Oct. 1, 1985, see section 8(a) of Pub. L. 99–91, set out as a note under section 360aa of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title; title 42 section 236.

[1] So in original. Probably should be followed by ''and''.

## PART C—ELECTRONIC PRODUCT RADIATION CONTROL

CODIFICATION

This part was classified to subpart 3 (§ 263c et seq.) of part F of subchapter II of chapter 6A of Title 42, The Public Health and Welfare, prior to its renumbering by Pub. L. 101–629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

PART REFERRED TO IN OTHER SECTIONS

This part is referred to in title 15 section 2080.

### § 360hh. Definitions

As used in this part—

(1) the term ''electronic product radiation'' means—

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

(2) the term ''electronic product'' means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation;

(3) the term ''manufacturer'' means any person engaged in the business of manufacturing, assembling, or importing of electronic products;

(4) the term ''commerce'' means (A) commerce between any place in any State and any place outside thereof; and (B) commerce wholly within the District of Columbia; and

(5) the term ''State'' includes the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa.

(June 25, 1938, ch. 675, § 531, formerly act July 1, 1944, ch. 373, title III, § 531, formerly § 355, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1174; amended Oct. 12, 1976, Pub. L. 94–484, title IX, § 905(b)(1), 90 Stat. 2325; renumbered § 531 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263c of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263c of Title 42, The Public Health and Welfare, as this section.

1990—Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart'' in introductory provisions.

1976—Par. (5). Pub. L. 94–484 defined ''State'' to include Northern Mariana Islands.

SHORT TITLE

For short title of Pub. L. 90–602, which enacted provisions now comprising this part (§§ 360hh to 360ss), as the ''Radiation Control for Health and Safety Act of 1968'', see section 1 of Pub. L. 90–602, set out as a Short Title of 1968 Amendments note under section 301 of this title.

TRANSFER OF SUBPART; CONSTRUCTION

Section 19(c) of Pub. L. 101–629 provided that: ''The transfer of subpart 3 of part F of title III of the Public Health Service Act [42 U.S.C. 263b et seq.] to the Federal Food, Drug, and Cosmetic Act [this chapter] does not change the application of the requirements of such subpart and such Act to electronic products which were in effect on the date of the enactment of this Act [Nov. 28, 1990].''

DEFINITION OF ''SECRETARY'' AND ''DEPARTMENT''

Section 3 of Pub. L. 90–602, as amended Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, provided that: ''As used in the amendments made by section 2 of this Act [enacting provisions now comprising sections 360hh to 360ss of this title], except when otherwise specified, the term 'Secretary' means the Secretary of Health and Human Services, and the term 'Department' means the Department of Health and Human Services.''

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Section 4 of Pub. L. 90–602 provided that: ''The amendments made by section 2 of this Act [enacting provisions now comprising sections 360hh to 360ss of this title] shall not be construed as superseding or limiting the functions, under any other provision of law, of any officer or agency of the United States.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360kk of this title; title 15 section 2080.

### § 360ii. Program of control

#### (a) Establishment

The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—

(1) pursuant to section 360kk of this title, develop and administer performance standards for electronic products;

(2) plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;

(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation;

(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) tech-

niques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions.

**(b) Powers of Secretary**

In carrying out the purposes of subsection (a) of this section, the Secretary is authorized to—

(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation; and (B) make such recommendations relating to such hazards and control as he considers appropriate;

(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a) of this section;

(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324 of title 31 and section 5 of title 41; and

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products.

**(c) Record keeping**

(1) Each recipient of assistance under this part pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under this part under other than competitive bidding procedures.

(June 25, 1938, ch. 675, § 532, formerly act July 1, 1944, ch. 373, title III, § 532, formerly § 356, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1174; renumbered § 532 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(A), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263d of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263d of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a)(1), (6). Pub. L. 101–629, § 19(a)(2)(A)(i), substituted ''section 360kk'' for ''section 263f''.

Subsec. (b)(3). Pub. L. 101–629, § 19(a)(2)(A)(ii), substituted reference to section 3324 of title 31 for reference to section 3648 of the Revised Statutes (31 U.S.C. 529).

Subsec. (c)(1), (2). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart''.

TRANSFER OF FUNCTIONS

Atomic Energy Commission abolished and functions transferred by sections 5814 and 5841 of Title 42, The Public Health and Welfare. See also Transfer of Functions notes set out under those sections.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law or any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

**§ 360jj. Studies by Secretary**

**(a) Report to Congress**

The Secretary shall conduct the following studies, and shall make a report or reports of the results of such studies to the Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate:

(1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to—

(A) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.];

(B) any gaps and inconsistencies in present controls;

(C) the need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products;

(D) measures to assure consistent and effective control of the aforementioned health hazards;

(E) measures to strengthen radiological health programs of State governments; and

(F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation;

(2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and

(3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from electronic products manufactured or imported prior to the effective date of any applicable standard established pursuant to this part.

**(b) Participation of other Federal agencies**

In carrying out these studies, the Secretary shall invite the participation of other Federal

departments and agencies having related responsibilities and interests, State governments—particularly those of States which regulate radioactive materials under section 274 of the Atomic Energy Act of 1954, as amended [42 U.S.C. 2021], and interested professional, labor, and industrial organizations. Upon request from congressional committees interested in these studies, the Secretary shall keep these committees currently informed as to the progress of the studies and shall permit the committees to send observers to meetings of the study groups.

**(c) Organization of studies and participation**

The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of the Secretary shall be included in the report if so requested by the dissenter.

(June 25, 1938, ch. 675, § 533, formerly act July 1, 1944, ch. 373, title III, § 533, formerly § 357, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1176; renumbered § 533 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

REFERENCES IN TEXT

The Atomic Energy Act of 1954, referred to in subsec. (a)(1)(A), is act Aug. 30, 1954, ch. 1073, § 1, 68 Stat. 921, as amended, which is classified generally to chapter 23 (§ 2011 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 2011 of Title 42 and Tables.

CODIFICATION

Section was classified to section 263e of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263e of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a)(3). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart''.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

## § 360kk. Performance standards for electronic products

**(a) Promulgation of regulations**

(1) The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products. Such standards may be prescribed from time to time whenever such determinations are made, but the first of such standards shall be prescribed prior to January 1, 1970. In the development of such standards, the Secretary shall consult with Federal and State departments and agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations which would be affected by such standards, and shall give consideration to—

(A) the latest available scientific and medical data in the field of electronic product radiation;

(B) the standards currently recommended by (i) other Federal agencies having responsibilities relating to the control and measurement of electronic product radiation, and (ii) public or private groups having an expertise in the field of electronic product radiation;

(C) the reasonableness and technical feasibility of such standards as applied to a particular electronic product;

(D) the adaptability of such standards to the need for uniformity and reliability of testing and measuring procedures and equipment; and

(E) in the case of a component, or accessory described in paragraph (2)(B) of section 360hh of this title, the performance of such article in the manufactured or assembled product for which it is designed.

(2) The Secretary may prescribe different and individual performance standards, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses.

(3) The performance standards prescribed under this section shall not apply to any electronic product which is intended solely for export if (A) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (B) such product meets all the applicable requirements of the country to which such product is intended for export.

(4) The Secretary may by regulation amend or revoke any performance standard prescribed under this section.

(5) The Secretary may exempt from the provisions of this section any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

**(b) Administrative procedure**

The provisions of subchapter II of chapter 5 of title 5 (relating to the administrative procedure for rulemaking), and of chapter 7 of title 5 (relating to judicial review), shall apply with respect to any regulation prescribing, amending, or revoking any standard prescribed under this section.

**(c) Publication in Federal Register**

Each regulation prescribing, amending, or revoking a standard shall specify the date on

which it shall take effect which, in the case of any regulation prescribing, or amending any standard, may not be sooner than one year or not later than two years after the date on which such regulation is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier or later date shall apply.

**(d) Judicial review**

(1) In a case of actual controversy as to the validity of any regulation issued under this section prescribing, amending, or revoking a performance standard, any person who will be adversely affected by such regulation when it is effective may at any time prior to the sixtieth day after such regulation is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such regulation. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based the regulation, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original regulation, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to review the regulation in accordance with chapter 7 of title 5 and to grant appropriate relief as provided in such chapter.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such regulation of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive, notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not substitution for any other remedies provided by law.

**(e) Availability of record**

A certified copy of the transcript of the record and administrative proceedings under this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, exclusion of imports, or other proceeding arising under or in respect of this part irrespective of whether proceedings with respect to the regulation have previously been initiated or become final under this section.

**(f) Technical Electronic Product Radiation Safety Standards Committee**

(1)(A) The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this part referred to as the ''Committee'') which he shall consult before prescribing any standard under this section. The Committee shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety, and shall be composed of fifteen members each of whom shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(i) Five members shall be selected from governmental agencies, including State and Federal Governments;

(ii) Five members shall be selected from the affected industries after consultation with industry representatives; and

(iii) Five members shall be selected from the general public, of which at least one shall be a representative of organized labor.

(B) The Committee may propose electronic product radiation safety standards to the Secretary for his consideration. All proceedings of the Committee shall be recorded and the record of each such proceeding shall be available for public inspection.

(2) Payments to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42 shall not render members of the Committee officers or employees of the United States for any purpose.

**(g) Review and evaluation**

The Secretary shall review and evaluate on a continuing basis testing programs carried out by industry to assure the adequacy of safeguards against hazardous electronic product radiation and to assure that electronic products comply with standards prescribed under this section.

**(h) Product certification**

Every manufacturer of an electronic product to which is applicable a standard in effect under this section shall furnish to the distributor or dealer at the time of delivery of such product, in the form of a label or tag permanently affixed to such product or in such manner as approved by the Secretary, the certification that such product conforms to all applicable standards under this section. Such certification shall be based upon a test, in accordance with such standard, of the individual article to which it is attached or upon a testing program which is in accord with good manufacturing practice and which has not been disapproved by the Secretary (in such manner as he shall prescribe by regulation) on the grounds that it does not assure the adequacy of safeguards against hazardous electronic prod-

uct radiation or that it does not assure that electronic products comply with the standards prescribed under this section.

(June 25, 1938, ch. 675, § 534, formerly act July 1, 1944, ch. 373, title III, § 534, formerly § 358, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1177; amended Oct. 30, 1970, Pub. L. 91–515, title VI, § 601(b)(2), (3), 84 Stat. 1311; renumbered § 534 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(B), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, §§ 3(w), 4(a)(2), 107 Stat. 778, 779.)

CODIFICATION

Section was classified to section 263f of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80, § 4(a)(2), amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263f of Title 42, The Public Health and Welfare, as this section.

Subsec. (f)(2). Pub. L. 103–80, § 3(w), made technical amendment to reference to section 210 of title 42 to reflect correction of corresponding provision of original act.

1990—Subsec. (a)(1)(E). Pub. L. 101–629, § 19(a)(2)(B), substituted ''section 360hh'' for ''section 263c''.

Subsecs. (e), (f)(1)(A). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart''.

1970—Subsec. (f)(2). Pub. L. 91–515 struck out provisions related to payment of compensation and travel expenses of members of the Committee who are not officers or employees of the United States, and substituted ''to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42'' for ''under this subsection''.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360ii, 360*ll*, 360mm, 360nn, 360*oo*, 360pp, 360ss of this title.

### § 360*ll*. Notification of defects in and repair or replacement of electronic products

**(a) Notification; exemption**

(1) Every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him has a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, or that an electronic product produced, assembled, or imported by him on or after the effective date of an applicable standard prescribed pursuant to section 360kk of this title fails to comply with such standard, shall immediately notify the Secretary of such defect or failure to comply if such product has left the place of manufacture and shall (except as authorized by paragraph (2)) with reasonable promptness furnish notification of such defect or failure to the persons (where known to the manufacturer) specified in subsection (b) of this section.

(2) If, in the opinion of such manufacturer, the defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he may, at the time of giving notice to the Secretary of such defect or failure to comply, apply to the Secretary for an exemption from the requirement of notice to the persons specified in subsection (b) of this section. If such application states reasonable grounds for such exemption, the Secretary shall afford such manufacturer an opportunity to present his views and evidence in support of the application, the burden of proof being on the manufacturer. If, after such presentation, the Secretary is satisfied that such defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he shall exempt such manufacturer from the requirement of notice to the persons specified in subsection (b) of this section and from the requirements of repair or replacement imposed by subsection (f) of this section.

**(b) Method of notification**

The notification (other than to the Secretary) required by paragraph (1) of subsection (a) of this section shall be accomplished—

(1) by certified mail to the first purchaser of such product for purposes other than resale, and to any subsequent transferee of such product; and

(2) by certified mail or other more expeditious means to the dealers or distributors of such manufacturer to whom such product was delivered.

**(c) Requisite elements of notification**

The notifications required by paragraph (1) of subsection (a) of this section shall contain a clear description of such defect or failure to comply with an applicable standard, an evaluation of the hazard reasonably related to such defect or failure to comply, and a statement of the measures to be taken to repair such defect. In the case of a notification to a person referred to in subsection (b) of this section, the notification shall also advise the person of his rights under subsection (f) of this section.

**(d) Copies to Secretary of communications by manufacturers to dealers or distributors regarding defects**

Every manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of such manufacturer or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any such defect in such product or any such failure to comply with a standard applicable to such product. The Secretary shall disclose to the public so much of the information contained in such notice or other information obtained under section 360nn of this title as he deems will assist in carrying out the purposes of this part, but he shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 unless he determines that it is necessary to carry out the purposes of this part.

**(e) Notice from Secretary to manufacturer of defects or failure to comply with standards**

If through testing, inspection, investigation, or research carried out pursuant to this part, or

examination of reports submitted pursuant to section 360nn of this title, or otherwise, the Secretary determines that any electronic product—

(1) does not comply with an applicable standard prescribed pursuant to section 360kk of this title; or

(2) contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation;

he shall immediately notify the manufacturer of such product of such defect or failure to comply. The notice shall contain the findings of the Secretary and shall include all information upon which the findings are based. The Secretary shall afford such manufacturer an opportunity to present his views and evidence in support thereof, to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of such radiation hazard. If after such presentation by the manufacturer the Secretary determines that such product does not comply with an applicable standard prescribed pursuant to section 360kk of this title, or that it contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, the Secretary shall direct the manufacturer to furnish the notification specified in subsection (c) of this section to the persons specified in paragraphs (1) and (2) of subsection (b) of this section (where known to the manufacturer), unless the manufacturer has applied for an exemption from the requirement of such notification on the ground specified in paragraph (2) of subsection (a) of this section and the Secretary is satisfied that such noncompliance or defect is not such as to create a significant risk of injury, including genetic injury, to any person.

**(f) Correction of defects**

If any electronic product is found under subsection (a) or (e) of this section to fail to comply with an applicable standard prescribed under this part or to have a defect which relates to the safety of use of such product, and the notification specified in subsection (c) of this section is required to be furnished on account of such failure or defect, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied, (2) replace such product with a like or equivalent product which complies with each applicable standard prescribed under this part and which has no defect relating to the safety of its use, or (3) make a refund of the cost of such product. The manufacturer shall take the action required by this subsection in such manner, and with respect to such persons, as the Secretary by regulations shall prescribe.

**(g) Effective date**

This section shall not apply to any electronic product that was manufactured before October 18, 1968.

(June 25, 1938, ch. 675, § 535, formerly act July 1, 1944, ch. 373, title III, § 535, formerly § 359, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1180; renumbered § 535 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(C), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263g of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263g of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a)(1). Pub. L. 101–629, § 19(a)(2)(C)(i), substituted ''section 360kk'' for ''section 263f''.

Subsec. (d). Pub. L. 101–629, § 19(a)(1)(B), (2)(C)(ii), substituted ''section 360nn'' for ''section 263i'' and ''this part'' for ''this subpart'' in two places.

Subsec. (e). Pub. L. 101–629, § 19(a)(1)(B), (2)(C), substituted ''this part'' for ''this subpart'' and ''section 360nn'' for ''section 263i'' in introductory provisions and ''section 360kk'' for ''section 263f'' in par. (1) and concluding provisions.

Subsec. (f). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart'' in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360nn, 360*oo* of this title.

## § 360mm. Imports

**(a) Refusal of admission to noncomplying electronic products**

Any electronic product offered for importation into the United States which fails to comply with an applicable standard prescribed under this part, or to which is not affixed a certification in the form of a label or tag in conformity with section 360kk(h) of this title shall be refused admission into the United States. The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon the latter's request, samples of electronic products which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may have a hearing before the Secretary of Health and Human Services. If it appears from an examination of such samples or otherwise that any electronic product fails to comply with applicable standards prescribed pursuant to section 360kk of this title, then, unless subsection (b) of this section applies and is complied with, (1) such electronic product shall be refused admission, and (2) the Secretary of the Treasury shall cause the destruction of such electronic product unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days after the date of notice of refusal of admission or within such additional time as may be permitted by such regulations.

**(b) Bond**

If it appears to the Secretary of Health and Human Services that any electronic product re-

fused admission pursuant to subsection (a) of this section can be brought into compliance with applicable standards prescribed pursuant to section 360kk of this title, final determination as to admission of such electronic product may be deferred upon filing of timely written application by the owner or consignee and the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as the Secretary of Health and Human Services may by regulation prescribe. If such application is filed and such bond is executed the Secretary of Health and Human Services may, in accordance with rules prescribed by him, permit the applicant to perform such operations with respect to such electronic product as may be specified in the notice of permission.

**(c) Liability of owner or consignee for expenses connected with refusal of admission**

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of operations provided for in subsection (b) of this section, and all expenses in connection with the storage, cartage, or labor with respect to any electronic product refused admission pursuant to subsection (a) of this section, shall be paid by the owner or consignee, and, in event of default, shall constitute a lien against any future importations made by such owner or consignee.

**(d) Designation of agent for purposes of service**

It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

(June 25, 1938, ch. 675, § 536, formerly act July 1, 1944, ch. 373, title III, § 536, formerly § 360, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1181; renumbered § 536 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(D), (3), (4), 104 Stat. 4529, 4530; June 16, 1992, Pub. L. 102–300, § 6(b)(1), 106 Stat. 240; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263h of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263h of Title 42, The Public Health and Welfare, as this section.

1992—Subsecs. (a), (b). Pub. L. 102–300 substituted ''Health and Human Services'' for ''Health, Education, and Welfare'' wherever appearing.

1990—Subsec. (a). Pub. L. 101–629, § 19(a)(1)(B), (2)(D), substituted ''this part'' for ''this subpart'', ''section 360kk(h)'' for ''section 263f(h)'', and ''section 360kk'' for ''section 263f''.

Subsec. (b). Pub. L. 101–629, § 19(a)(2)(D), substituted ''section 360kk'' for ''section 263f''.

Subsec. (d). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart'' in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

## § 360nn. Inspection, records, and reports

**(a) Inspection of premises**

If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times, any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 360kk(h) of this title are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this part and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 360*ll*(a)(2) or 360*ll*(e) of this title.

**(b) Record keeping**

Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this part and standards prescribed pursuant to this part and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this part.

**(c) Disclosure of technical data**

Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this part. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this part after consulting with the affected industry.

**(d) Public nature of reports**

Accident and investigation reports made under this part by any officer, employee, or agent of the Secretary shall be available for use in any civil, criminal, or other judicial proceeding arising out of such accident. Any such officer, employee, or agent may be required to testify in such proceedings as to the facts developed in such investigations. Any such report shall be made available to the public in a manner which need not identify individuals. All reports on research projects, demonstration projects, and other related activities shall be public information.

**(e) Trade secrets**

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to subsection (a) or (b) of this section, which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18, except that such information may be disclosed to other officers or employees of the Department and of other agencies concerned with carrying out this part or when relevant in any proceeding under this part. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

**(f) Information required to identify and locate first purchasers of electronic products**

The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this part and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 360*ll* of this title, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer, to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 360*ll* of this title, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of section 360*ll* of this title, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 360*ll*(a) of this title.

(June 25, 1938, ch. 675, § 537, formerly act July 1, 1944, ch. 373, title III, § 537, formerly § 360A, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1182; renumbered § 537 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(E), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263i of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263i of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a). Pub. L. 101–629, § 19(a)(1)(B), (2)(E), substituted ''section 360kk(h)'' for ''section 263f(h)'', ''this part'' for ''this subpart'', and ''section 360*ll*(a)(2) or 360*ll*(e)'' for ''section 263g(a)(2) or 263g(e)''.

Subsecs. (b) to (e). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart'' wherever appearing.

Subsec. (f). Pub. L. 101–629, § 19(a)(1)(B), (2)(E)(ii), substituted ''this part'' for ''this subpart'', ''section 360*ll*'' for ''section 263g'' in three places, and ''section 360*ll*(a)'' for ''section 263g(a)''.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360*ll*, 360*oo* of this title.

## § 360*oo*. Prohibited acts

(a) It shall be unlawful—

(1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 360kk of this title;

(2) for any person to fail to furnish any notification or other material or information required by section 360*ll* or 360nn of this title; or to fail to comply with the requirements of section 360*ll*(f) of this title;

(3) for any person to fail or to refuse to establish or maintain records required by this part or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 360nn of this title;

(4) for any person to fail or to refuse to make any report required pursuant to section 360nn(b) of this title or to furnish or preserve any information required pursuant to section 360nn(f) of this title; or

(5) for any person (A) to fail to issue a certification as required by section 360kk(h) of this title, or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 360kk(h) of this title or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a) of this section, upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.

(June 25, 1938, ch. 675, § 538, formerly act July 1, 1944, ch. 373, title III, § 538, formerly § 360B, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1184; renumbered § 538 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(F), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263j of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263j of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a)(1). Pub. L. 101–629, § 19(a)(2)(F)(i), substituted ''section 360kk'' for ''section 263f''.

Subsec. (a)(2). Pub. L. 101–629, § 19(a)(2)(F)(ii), (iii), substituted ''section 360*ll* or 360nn'' for ''section 263g or 263i'' and ''section 360*ll*(f)'' for ''section 263g(f)''.

Subsec. (a)(3). Pub. L. 101–629, § 19(a)(1)(B), (2)(F)(iii), substituted ''this part'' for ''this subpart'' and ''section 360nn'' for ''section 263i''.

Subsec. (a)(4). Pub. L. 101–629, § 19(a)(2)(F)(iii), substituted ''section 360nn(b)'' for ''section 263i(b)'' and ''section 360nn(f)'' for ''section 263i(f)''.

Subsec. (a)(5). Pub. L. 101–629, § 19(a)(2)(F)(i), substituted ''section 360kk(h)'' for ''section 263f(h)'' in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360pp of this title.

## § 360pp. Enforcement

### (a) Jurisdiction of courts

The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of section 360*oo* of this title and to restrain dealers and distributors of electronic products from selling or otherwise disposing of electronic products which do not conform to an applicable standard prescribed pursuant to section 360kk of this title except when such products are disposed of by returning them to the distributor or manufacturer from whom they were obtained. The district courts of the United States shall also have jurisdiction in accordance with section 1355 of title 28 to enforce the provisions of subsection (b) of this section.

### (b) Penalties

(1) Any person who violates section 360*oo* of this title shall be subject to a civil penalty of not more than $1,000. For purposes of this subsection, any such violation shall with respect to each electronic product involved, or with respect to each act or omission made unlawful by section 360*oo* of this title, constitute a separate violation, except that the maximum civil penalty imposed on any person under this subsection for any related series of violations shall not exceed $300,000.

(2) Any such civil penalty may on application be remitted or mitigated by the Secretary. In determining the amount of such penalty, or whether it should be remitted or mitigated and in what amount, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of such penalty, when finally determined, may be deducted from any sums owing by the United States to the person charged.

### (c) Venue; process

Actions under subsections (a) and (b) of this section may be brought in the district court of the United States for the district wherein any act or omission or transaction constituting the violation occurred, or in such court for the district where the defendant is found or transacts business, and process in such cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

### (d) Warnings

Nothing in this part shall be construed as requiring the Secretary to report for the institution of proceedings minor violations of this part whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

### (e) Compliance with regulations

Except as provided in the first sentence of section 360ss of this title, compliance with this part or any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law.

### (f) Additional remedies

The remedies provided for in this part shall be in addition to and not in substitution for any other remedies provided by law.

(June 25, 1938, ch. 675, § 539, formerly act July 1, 1944, ch. 373, title III, § 539, formerly § 360C, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1184; renumbered § 539 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(G), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263k of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263k of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a). Pub. L. 101–629, § 19(a)(2)(G)(i), (ii), substituted ''section 360*oo*'' for ''section 263j'' and ''section 360kk'' for ''section 263f''.

Subsec. (b)(1). Pub. L. 101–629, § 19(a)(2)(G)(ii), substituted ''section 360*oo*'' for ''section 263j'' in two places.

Subsec. (d). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart'' in two places.

Subsec. (e). Pub. L. 101–629, § 19(a)(1)(B), (2)(G)(iii), substituted ''section 360ss'' for ''section 263n'' and ''this part'' for ''this subpart''.

Subsec. (f). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart''.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

### § 360qq. Annual report

(a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part for the preceding calendar year. Such report shall include—

(1) a thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury and effects, including genetic effects, to the population resulting from exposure to electronic product radiation, with a breakdown, insofar as practicable, among the various sources of such radiation;

(2) a list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year;

(3) an evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name;

(4) a summary of outstanding problems confronting the administration of this part in order of priority;

(5) an analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year;

(6) a list, with a brief statement of the issues, of completed or pending judicial actions under this part;

(7) the extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer-oriented information was made available to the public; and

(8) the extent of cooperation between Government officials and representatives of industry and other interested parties in the implementation of this part including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

(b) The report required by subsection (a) of this section shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program.

(June 25, 1938, ch. 675, § 540, formerly act July 1, 1944, ch. 373, title III, § 540, formerly § 360D, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1185; renumbered § 540 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263*l* of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263*l* of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a). Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart'' wherever appearing.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

### § 360rr. Federal-State cooperation

The Secretary is authorized (1) to accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this part which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance, and (2) he may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any such authority as an officer of the Department.

(June 25, 1938, ch. 675, § 541, formerly act July 1, 1944, ch. 373, title III, § 541, formerly § 360E, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1186; renumbered § 541 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263m of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263m of Title 42, The Public Health and Welfare, as this section.

1990—Pub. L. 101–629, § 19(a)(1)(B), substituted ''this part'' for ''this subpart''.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

### § 360ss. State standards

Whenever any standard prescribed pursuant to section 360kk of this title with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this part shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.

(June 25, 1938, ch. 675, § 542, formerly act July 1, 1944, ch. 373, title III, § 542, formerly § 360F, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1186; renumbered § 542 and amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), (2)(H), (3), (4), 104 Stat. 4529, 4530; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779.)

CODIFICATION

Section was classified to section 263n of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, § 19(a)(4), which renumbered section 263n of Title 42, The Public Health and Welfare, as this section.

1990—Pub. L. 101–629, § 19(a)(1)(B), (2)(H), substituted ''section 360kk'' for ''section 263f'' and ''this part'' for ''this subpart''.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360pp of this title.

## SUBCHAPTER VI—COSMETICS

### § 361. Adulterated cosmetics

A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: ''Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.'', and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term ''hair dye'' shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(June 25, 1938, ch. 675, § 601, 52 Stat. 1054; July 12, 1960, Pub. L. 86–618, title I, § 102(c)(1), 74 Stat. 398; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(11), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103–80, § 3(x), 107 Stat. 778.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–80 substituted ''usual, except that this'' for ''usual: *Provided*, That this''.

1992—Par. (e). Pub. L. 102–571 substituted ''379e(a)'' for ''376(a)''.

1960—Par. (e). Pub. L. 86–618 substituted ''and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376(a) of this title'' for ''and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 364 of this title''.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE; POSTPONEMENT

Par. (e) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

EFFECTIVE DATE

Section effective twelve months after June 25, 1938, except par. (a), which, with certain exceptions, became effective on June 25, 1938, see section 902(a) of act June 25, 1938, set out as a note under section 301 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 379e of this title.

### § 362. Misbranded cosmetics

A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 361(a) of this title).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(June 25, 1938, ch. 675, § 602, 52 Stat. 1054; July 12, 1960, Pub. L. 86–618, title I, § 102(c)(2), 74 Stat. 398; Dec. 30, 1970, Pub. L. 91–601, § 6(f), formerly § 7(f), 84 Stat. 1673, renumbered Aug. 13, 1981, Pub. L. 97–35, title XII, § 1205(c), 95 Stat. 716; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(12), 106 Stat. 4499.)

AMENDMENTS

1992—Par. (e). Pub. L. 102–571 substituted ''379e'' for ''376''.

1970—Par. (f). Pub. L. 91–601 added par. (f).

1960—Par. (e). Pub. L. 86–618 added par. (e).

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE; POSTPONEMENT

Par. (b) effective Jan. 1, 1940, and such subsection effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title.

### § 363. Regulations making exemptions

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(June 25, 1938, ch. 675, § 603, 52 Stat. 1054.)

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

### § 364. Repealed. Pub. L. 86–618, title I, § 103(a)(3), July 12, 1960, 74 Stat. 398

Section, act June 25, 1938, ch. 675, § 604, 52 Stat. 1055, directed Secretary to promulgate regulations for listing of coal-tar colors for cosmetics. See section 379e of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as an Effective Date of 1960 Amendment note under section 379e of this title.

## SUBCHAPTER VII—GENERAL AUTHORITY

## PART A—GENERAL ADMINISTRATIVE PROVISIONS

### § 371. Regulations and hearings

**(a) Authority to promulgate regulations**

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

**(b) Regulations for imports and exports**

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

**(c) Conduct of hearings**

Hearings authorized or required by this chapter shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

**(d) Effectiveness of definitions and standards of identity**

The definitions and standards of identity promulgated in accordance with the provisions of

this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

**(e) Procedure for establishment**

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

**(f) Review of order**

(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

**(g) Copies of records of hearings**

A certified copy of the transcript of the record and proceedings under subsection (e) of this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have pre-

viously been instituted or become final under subsection (f) of this section.

(June 25, 1938, ch. 675, § 701, 52 Stat. 1055; June 25, 1948, ch. 646, § 32, 62 Stat. 991; Apr. 15, 1954, ch. 143, § 2, 68 Stat. 55; Aug. 1, 1956, ch. 861, § 2, 70 Stat. 919; Aug. 28, 1958, Pub. L. 85–791, § 21, 72 Stat. 948; July 12, 1960, Pub. L. 86–618, title I, § 103(a)(4), 74 Stat. 398; Nov. 8, 1990, Pub. L. 101–535, § 8, 104 Stat. 2365; June 16, 1992, Pub. L. 102–300, § 6(b)(1), 106 Stat. 240; Aug. 13, 1993, Pub. L. 103–80, §§ 3(y), (dd)(1), 4(c), 107 Stat. 778, 779; Oct. 22, 1994, Pub. L. 103–396, § 3(b), 108 Stat. 4155.)

AMENDMENTS

1994—Subsec. (e)(1). Pub. L. 103–396 which directed the amendment of par. (1) by striking out ''or maple syrup (regulated under section 168.140 of title 21, Code of Federal Regulations).'', was executed by striking out ''or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)'' before ''shall be begun by a proposal'', to reflect the probable intent of Congress.

1993—Subsec. (b). Pub. L. 103–80, § 3(dd)(1), substituted ''Health and Human Services'' for ''Agriculture'' in two places.

Subsec. (e)(1). Pub. L. 103–80, § 4(c), made technical correction to directory language of Pub. L. 101–535, § 8. See 1990 Amendment note below.

Pub. L. 103–80, § 3(y)(1), struck out period after second reference to ''Regulations)''.

Subsec. (f)(4). Pub. L. 103–80, § 3(y)(2), substituted reference to section 1254 of title 28 for ''sections 239 and 240 of the Judicial Code, as amended''.

1992—Subsec. (b). Pub. L. 102–300, which directed the substitution of ''Health and Human Services'' for ''Health, Education, and Welfare'', could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions note below.

1990—Subsec. (e)(1). Pub. L. 101–535, § 8, as amended by Pub. L. 103–80, § 4(c), substituted ''Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)'' for ''Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title''.

1960—Subsec. (e). Pub. L. 86–618 substituted ''section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title'' for ''section 341, 343(j), 344(a), 346(a) or (b), 351(b), 352(d) or (h), 354 or 364 of this title''.

1958—Subsec. (f)(1). Pub. L. 85–791, § 21(a), substituted provisions requiring transmission of a copy of the petition by clerk to Secretary, and filing of the record by Secretary, for provisions which permitted service of summons and petition any place in United States and required Secretary to certify and file transcript of the proceedings and record upon service.

Subsec. (f)(3). Pub. L. 85–791, § 21(b), inserted ''Upon the filing of the petition referred to in paragraph (1) of this subsection''.

1956—Subsec. (e). Act Aug. 1, 1956, simplified procedures governing prescribing of regulations under certain provisions of this chapter.

1954—Subsec. (e). Act Apr. 15, 1954, struck out reference to section 341 of this title, before ''343(j)'', such section 341 now containing its own provisions with respect to hearings regarding the establishment of food standards.

CHANGE OF NAME

Circuit Court of Appeals of the United States changed to United States court of appeals by act June 25, 1948, eff. Sept. 1, 1948.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

SAVINGS PROVISION

Savings clause of act Aug. 1, 1956, see note set out under section 341 of this title.

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101–535

Amendments by Pub. L. 101–535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101–535, set out as a note under section 343 of this title.

HEARINGS PENDING ON APRIL 15, 1954, WITH RESPECT TO FOOD STANDARDS

Provisions of this chapter in effect prior to Apr. 15, 1954, as applicable with respect to hearings begun prior to such date under subsection (e) of this section, regarding food standards, see Savings Provisions note set out under section 341 of this title.

FEDERAL RULES OF CIVIL PROCEDURE

Admiralty and maritime rules of practice (which included libel procedures) were superseded, and civil and admiralty procedures in United States district courts were unified, effective July 1, 1966, see rule 1 and Supplemental Rules for Certain Admiralty and Maritime Claims, Title 28, Appendix, Judiciary and Judicial Procedure.

CROSS REFERENCES

Pesticide chemical regulations, see section 346a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 346a, 352, 356, 357, 379e of this title; title 15 sections 1261, 1262, 1455, 1474.

## § 372. Examinations and investigations

### (a) Authority to conduct

The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions

of this chapter, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term ''United States'' means the States and the District of Columbia.

**(b) Availability to owner of part of analysis samples**

Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

**(c) Records of other departments and agencies**

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection.

**(d) Information on patents for drugs**

The Secretary is authorized and directed, upon request from the Commissioner of Patents and Trademarks, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

**(e) Powers of enforcement personnel**

Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this chapter relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 334 of this title;

(4) make arrests without warrant for offenses under this chapter with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 334(a)(2) of this title, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 334(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 334(a)(2) of this title shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

(June 25, 1938, ch. 675, § 702, 52 Stat. 1056; Oct. 10, 1962, Pub. L. 87–781, title III, §§ 307(b), 308, 76 Stat. 796; July 15, 1965, Pub. L. 89–74, § 8(a), 79 Stat. 234; Oct. 27, 1970, Pub. L. 91–513, title II, § 701(f), 84 Stat. 1282; Jan. 2, 1975, Pub. L. 93–596, § 3, 88 Stat. 1949; June 16, 1992, Pub. L. 102–300, § 6(b)(2), 106 Stat. 240; Aug. 13, 1993, Pub. L. 103–80, § 3(dd)(2), 107 Stat. 779.)

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–80 struck out ''of Agriculture'' after ''Department''.

1992—Subsec. (c). Pub. L. 102–300, which directed the amendment of subsec. (c) by striking out ''of Health, Education, and Welfare'', could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions note below.

1970—Subsec. (e). Pub. L. 91–513 struck out reference to depressant or stimulant drugs.

1965—Subsec. (e). Pub. L. 89–74 added subsec. (e).

1962—Subsec. (a). Pub. L. 87–781, § 307(b), inserted ''the Commonwealth of Puerto Rico or'' before ''a Territory the Secretary''.

Subsec. (d). Pub. L. 87–781, § 308, added subsec. (d).

CHANGE OF NAME

''Commissioner of Patents and Trademarks'' substituted for ''Commissioner of Patents'' in subsec. (d) pursuant to section 3 of Pub. L. 93–596, set out as a note under section 1 of Title 35, Patents.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective July 15, 1965, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

FEDERAL RULES OF CIVIL PROCEDURE

Admiralty and maritime rules of practice (which included libel procedures) were superseded, and civil and admiralty procedures in United States district courts were unified, effective July 1, 1966, see rule 1 and Supplemental Rules for Certain Admiralty and Maritime Claims, Title 28, Appendix, Judiciary and Judicial Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title.

## § 372a. Transferred

CODIFICATION

Section, act June 25, 1938, ch. 675, § 702A, formerly June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch.

712, 48 Stat. 1204, and amended, which related to examination of sea food, was renumbered section 706 of act June 25, 1938, by Pub. L. 102–571, title I, § 106(3), Oct. 29, 1992, 106 Stat. 4498, and transferred to section 376 of this title.

### § 373. Records of interstate shipment

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates, except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

(June 25, 1938, ch. 675, § 703, 52 Stat. 1057; Oct. 15, 1970, Pub. L. 91–452, title II, § 230, 84 Stat. 930; Aug. 13, 1993, Pub. L. 103–80, § 3(z), 107 Stat. 778.)

AMENDMENTS

1993—Pub. L. 103–80 substituted ‘‘, except that’’ for ‘‘: *Provided*, That’’ and ‘‘, and except that’’ for ‘‘: *Provided further*, That’’.

1970—Pub. L. 91–452 inserted ‘‘, or any evidence which is directly or indirectly derived from such evidence,’’ after ‘‘under this section’’.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–452 effective on sixtieth day following Oct. 15, 1970, and not to affect any immunity to which any individual is entitled under this section by reason of any testimony given before sixtieth day following Oct. 15, 1970, see section 260 of Pub. L. 91–452, set out as an Effective Date; Savings Provision note under section 6001 of Title 18, Crimes and Criminal Procedure.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

CROSS REFERENCES

Immunity of witnesses, see section 6001 et seq. of Title 18, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 331 of this title.

### § 374. Inspection

#### (a) Right of agents to enter; scope of inspection; notice; promptness; exclusions

(1) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (k), section 357(d) or (g), section 360i, or 360j(g) of this title, and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(2) The provisions of the second sentence of paragraph (1) shall not apply to—

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate,

compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices, solely for use in the course of their professional practice;

(C) persons who manufacture, prepare, propagate, compound, or process drugs or manufacture or process devices, solely for use in research, teaching, or chemical analysis and not for sale;

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 350a of this title applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 350a of this title, or

(B) required to be maintained under section 350a of this title.

**(b) Written report to owner; copy to Secretary**

Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

**(c) Receipt for samples taken**

If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

**(d) Analysis of samples furnished owner**

Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

**(e) Accessibility of records**

Every person required under section 360i or 360j(g) of this title to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

(June 25, 1938, ch. 675, §704, 52 Stat. 1057; Aug. 7, 1953, ch. 350, §1, 67 Stat. 476; Oct. 10, 1962, Pub. L. 87–781, title II, §201(a), (b), 76 Stat. 792, 793; May 28, 1976, Pub. L. 94–295, §6, 90 Stat. 581; Sept. 26, 1980, Pub. L. 96–359, §4, 94 Stat. 1193; Aug. 13, 1993, Pub. L. 103–80, §3(aa), 107 Stat. 778.)

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–80 substituted a comma for semicolon after ''finished and unfinished materials'' and ''section 355(i) or (k)'' for ''section 355(i) or (j)''.

1980—Subsec. (a)(1). Pub. L. 96–359, §4(1), (2), restructured first five sentences of former subsec. (a) as par. (1) and, as so restructured, inserted reference to paragraph (3) and substituted ''(A)'' and ''(B)'' for ''(1)'' and ''(2)'', respectively.

Subsec. (a)(2). Pub. L. 96–359, §4(3), redesignated sixth sentence of former subsec. (a) as par. (2) and, as so redesignated, substituted reference to second sentence of paragraph (1) for reference to former second sentence of this subsection, and ''(A)'', ''(B)'', ''(C)'', and ''(D)'', for ''(1)'', ''(2)'', ''(3)'', and ''(4)'', respectively.

Subsec. (a)(3). Pub. L. 96–359, §4(4), added par. (3).

1976—Subsec. (a). Pub. L. 94–295, §6(a)–(c), expanded existing provisions to encompass medical devices by inserting references to factories, warehouses, establishments, and consulting laboratories in which restricted devices are manufactured, processed, packed, or held, inspections relating to devices, reporting and inspection regulations issued pursuant to sections 360i and 360j(g) of this title, and the manufacture and processing of devices.

Subsec. (e). Pub. L. 94–295, §6(d), added subsec. (e).

1962—Subsec. (a). Pub. L. 87–781, §201(a), extended the inspection, where prescription drugs are manufactured, processed, packed, or held, to all things bearing on whether adulterated or misbranded drugs, or any which may not be manufactured, introduced in interstate commerce, or sold or offered for sale under any provision of this chapter, have been or are being manufactured, processed, packed, transported or held in any such place, or otherwise bearing on violation of this chapter, but excluded from such inspection, data concerning finance, sales other than shipment, pricing, personnel other than qualifications of technical and professional personnel, research other than relating to new drugs subject to reporting, provided that provisions of second sentence of this subsection shall be inapplicable to pharmacies, practitioners and other persons enumerated in pars. (1) to (4), and struck out ''are held'' before ''after such introduction''.

Subsec. (b). Pub. L. 87–781, §201(b), inserted ''consulting laboratory'' after ''warehouse''.

1953—Act Aug. 7, 1953, designated existing provisions as subsec. (a) and amended them by substituting provisions permitting entry and inspection upon presentation of appropriate credentials and a written notice to the owner, operator, or agent in charge for provisions which authorized entry and inspection only after making a request and obtaining permission from the owner, operator, or custodian, and inserting provisions requiring a separate written notice for each inspection but not for each entry made during the period covered by the inspection, and directing that the inspection

shall be conducted within reasonable limits, in a reasonable manner and completed with reasonable promptness, and added subsecs. (b) to (d).

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–781 effective Oct. 10, 1962, see section 203 of Pub. L. 87–781, set out as a note under section 332 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

AUTHORITY OF SECRETARY PRIOR TO OCTOBER 10, 1962

Section 201(d) of Pub. L. 87–781 provided that: ''Nothing in the amendments made by subsections (a) and (b) of this section [amending this section] shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act [Oct. 10, 1962].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 334, 360, 360e, 360j of this title.

## § 375. Publicity

### (a) Reports

The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

### (b) Information regarding certain goods

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

(June 25, 1938, ch. 675, § 705, 52 Stat. 1057.)

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360h of this title.

## § 376. Examination of sea food on request of packer; marking food with results; fees; penalties

The Secretary, upon application of any packer of any sea food for shipment or sale within the jurisdiction of this chapter, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this chapter and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained, and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine.

(June 25, 1938, ch. 675, § 706, formerly § 702A, formerly June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204; amended Aug. 27, 1935, ch. 739, 49 Stat. 871; June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059; renumbered § 702A of act June 25, 1938, July 12, 1943, ch. 221, title II, 57 Stat. 500; June 16, 1992, Pub. L. 102–300, § 6(b)(2), 106 Stat. 240; renumbered § 706, Oct. 29, 1992, Pub. L. 102–571, title I, § 106(3), 106 Stat. 4498; Aug. 13, 1993, Pub. L. 103–80, § 3(dd)(2), 107 Stat. 779.)

CODIFICATION

Section was formerly classified to section 372a of this title prior to renumbering by Pub. L. 102–571.

Section, which formerly was not a part of the Federal Food, Drug, and Cosmetic Act, originally was classified to section 14a of this title. Section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that the section should remain in force and effect and be applicable to the provisions of this chapter. Act July 12, 1943, renumbered this section as 702A of the Federal Food, Drug, and Cosmetic Act.

PRIOR PROVISIONS

A prior section 376, act June 25, 1938, ch. 675, § 706, 52 Stat. 1058, as amended, which related to listing and certification of color additives for foods, drugs, devices, and cosmetics, was renumbered section 721 of act June 25, 1938, by Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498, and transferred to section 379e of this title.

AMENDMENTS

1993—Pub. L. 103–80 struck out ''of Agriculture'' after ''Secretary'' in two places.

1992—Pub. L. 102–300, which directed the amendment of the section by striking out ''of Health, Education, and Welfare'' wherever appearing, could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions note below.

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V,

§ 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

### § 377. Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests

The Secretary, in carrying into effect the provisions of this chapter, is authorized on and after July 12, 1943, to cooperate with associations and scientific societies in the revision of the United States Pharmacopoeia and in the development of methods of analysis and mechanical and physical tests necessary to carry out the work of the Food and Drug Administration.

(July 12, 1943, ch. 221, title II, 57 Stat. 500; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

CODIFICATION

Section was enacted as part of the Labor-Federal Security Appropriation Act, 1944, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

### § 378. Advertising of foods

#### (a) Determination of misbranding; notification of Federal Trade Commission by Secretary; contents

(1) Except as provided in subsection (c) of this section, before the Secretary may initiate any action under subchapter III of this chapter—

(A) with respect to any food which the Secretary determines is misbranded under section 343(a)(2) of this title because of its advertising, or

(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded,

the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

(2) The notice required by paragraph (1) shall—

(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

#### (b) Action by Federal Trade Commission precluding action by Secretary; exception

(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of this section of action proposed to be taken under subchapter III of this chapter with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

(A) it has initiated under the Federal Trade Commission Act [15 U.S.C. 41 et seq.] an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 [15 U.S.C. 45, 53, or 57b] with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 [15 U.S.C. 45] with respect to such advertising,

(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act [15 U.S.C. 45(b)] respecting such advertising, or

(D) pursuant to section 16(b) of such Act [15 U.S.C. 56(b)] it has made a certification to the Attorney General respecting such advertising,

the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a) of this section—

(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a) of this section. The Commission shall promptly notify the Secretary of the commencement by the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

**(c) Secretary's determination of imminent hazard to health as suspending applicability of provisions**

The requirements of subsections (a) and (b) of this section do not apply with respect to action under subchapter III of this chapter with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

**(d) Coordination of action by Secretary with Federal Trade Commission**

For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under subchapter III of this chapter because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act [15 U.S.C. 41 et seq.] with respect to such advertising.

(June 25, 1938, ch. 675, § 707, as added Apr. 22, 1976, Pub. L. 94–278, title V, § 502(b), 90 Stat. 412.)

REFERENCES IN TEXT

The Federal Trade Commission Act, referred to in subsecs. (b) and (d), is act Sept. 26, 1914, ch. 311, 38 Stat. 717, as amended, which is classified generally to subchapter I (§ 41 et seq.) of chapter 2 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see section 58 of Title 15 and Tables.

### § 379. Confidential information

The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this chapter, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

(June 25, 1938, ch. 675, § 708, as added May 28, 1976, Pub. L. 94–295, § 8, 90 Stat. 582.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 331 of this title.

### § 379a. Presumption of existence of jurisdiction

In any action to enforce the requirements of this chapter respecting a device the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

(June 25, 1938, ch. 675, § 709, as added May 28, 1976, Pub. L. 94–295, § 8, 90 Stat. 583.)

### § 379b. Consolidated administrative and laboratory facility

**(a) Authority**

The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

**(b) Awarding of contract**

The Secretary shall solicit contract proposals under subsection (a) of this section from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

**(c) Donations**

In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the Food and Drug Administration gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

**(d) Authorization of appropriations**

There are authorized to be appropriated to carry out this section $100,000,000 for fiscal year 1991, and such sums as may be necessary for each of the subsequent fiscal years, to remain available until expended.

(June 25, 1938, ch. 675, § 710, as added Nov. 28, 1990, Pub. L. 101–635, title I, § 101, 104 Stat. 4583.)

### § 379c. Transferred

CODIFICATION

Section, act June 25, 1938, ch. 675, § 711, as added Nov. 28, 1990, Pub. L. 101–635, title II, § 201, 104 Stat. 4584, which related to recovery and retention of fees for freedom of information requests, was renumbered section 731 of act June 25, 1938, by Pub. L. 102–571, title I, § 106(6), Oct. 29, 1992, 106 Stat. 4499, and transferred to section 379f of this title.

### § 379d. Automation of Food and Drug Administration

**(a) In general**

The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this chapter.

**(b) Authorization of appropriations**

There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, § 711, formerly § 712, as added Nov. 28, 1990, Pub. L. 101–635, title IV, § 401, 104 Stat. 4585; renumbered § 711, Oct. 29, 1992, Pub. L. 102–571, title I, § 106(3), 106 Stat. 4498.)

PRIOR PROVISIONS

A prior section 711 of act June 25, 1938, was renumbered section 731 by Pub. L. 102–571 and is classified to section 379f of this title.

PART B—COLORS

## § 379e. Listing and certification of color additives for foods, drugs, devices, and cosmetics

### (a) Unsafe color additives

A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 342(c), 351(a)(4), or 361(e) of this title, as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) of this section, for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) of this section with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 342(a) of this title if such article is a food, or within the meaning of section 361(a) of this title if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 361(a) of this title). A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.

### (b) Listing of colors; regulations; issuance, amendment or repeal; referral to advisory committee; report and recommendations; appointment and compensation of advisory committee

(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, or devices, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2)(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs or devices, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however*, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term ''food additive'' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 321(s) of this title.

(5)(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug or device, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or ani-

mal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal: *Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) of this section) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

(C)(i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 371(e) of this title if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

(iii) Where—

(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of any advisory committee established under this chapter, while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule, including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this chapter or would otherwise result in misbranding or adulteration within the meaning of this chapter.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure

that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

**(c) Certification of colors**

The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) of this section and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

**(d) Procedure for issuance, amendment, or repeal of regulations**

The provisions of section 371(e), (f), and (g) of this title shall, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 371(e) of this title) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 556(d) of title 5. The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 348(f)(2) of this title; and

(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 348(g) of this title.

**(e) Fees**

The admitting to listing and certification of color additives, in accordance with regulations prescribed under this chapter, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

**(f) Exemptions**

The Secretary shall by regulations (issued without regard to subsection (d) of this section) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or device, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(June 25, 1938, ch. 675, §721, formerly §706, 52 Stat. 1058; July 12, 1960, Pub. L. 86–618, title I, §103(b), 74 Stat. 399; Oct. 10, 1962, Pub. L. 87–781, title I, §104(f)(2), 76 Stat. 785; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(d)(2), 84 Stat. 1311; May 28, 1976, Pub. L. 94–295, §9(a), 90 Stat. 583; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; June 16, 1992, Pub. L. 102–300, §6(b)(2), 106 Stat. 240; renumbered §721, Oct. 29, 1992, Pub. L.

102–571, title I, § 106(4), 106 Stat. 4498; Aug. 13, 1993, Pub. L. 103–80, § 3(bb), 107 Stat. 778.)

CODIFICATION

Section was formerly classified to section 376 of this title prior to renumbering by Pub. L. 102–571.

In subsec. (d)(2), ''section 556(d) of title 5'' substituted for ''section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))'' on authority of Pub. L. 89–554, § 7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1993—Subsec. (b)(5)(D). Pub. L. 103–80 substituted ''section 5703'' for ''section 5703(b)''.

1992—Subsec. (b)(5)(C)(i). Pub. L. 102–300 struck out ''of Health, Education, and Welfare'' after ''representatives of the Department''.

1976—Subsec. (a). Pub. L. 94–295, § 9(a)(2), (3), inserted reference to devices and inserted provisions directing that color additives for use in or on devices be subject to this section only if the color additives come in direct contact with the body of man or other animals for a significant period of time and authorizing the Secretary to designate by regulation the uses of color additives in or on devices which are subject to this section.

Subsec. (b). Pub. L. 94–295, § 9(a)(1), (2), substituted ''drug or device'' for ''drug'' and ''drugs or devices'' for ''drugs'' wherever appearing.

Subsec. (f). Pub. L. 94–295, § 9(a)(1), substituted ''drug or device'' for ''drug''.

1970—Subsec. (b)(5)(D). Pub. L. 91–515 substituted provisions authorizing members of an advisory committee to receive compensation at rates fixed by the Secretary, with a specific maximum amount, and travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of Title 5, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1962—Subsec. (b)(5)(B). Pub. L. 87–781 provided that clause (i) of this subparagraph shall not apply to a color additive in feed of animals raised for food production, if under the conditions of use specified in proposed labeling, and which conditions are reasonably certain to be followed in practice, such additive will not adversely affect the animals and no residue will be found in any edible portion of such animal after slaughter or in any food from the living animal.

1960—Pub. L. 86–618 amended section generally. Prior to amendment, section read as follows: ''The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this chapter, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.''

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–781 effective Oct. 10, 1962, see section 107 of Pub. L. 87–781, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Title II of Pub. L. 86–618 provided that:

''SEC. 201. [DEFINITIONS.] As used in this title, the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter]; the term 'enactment date' means the date of enactment of this Act [July 12, 1960]; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

''SEC. 202. [EFFECTIVE DATE.] This Act [amending this section and sections 321, 331, 333, 342, 343, 346, 351, 352, 361, 362, and 371 of this title and repealing sections 354 and 364 of this title] shall, subject to the provisions of section 203, take effect on the enactment date [July 12, 1960].

''SEC. 203. [PROVISIONAL LISTINGS OF COMMERCIALLY ESTABLISHED COLORS.] (a)(1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 [now 721] of the basic Act, [this section], whichever date first occurs.

''(2) For the purposes of this section, the term 'closing date' means (A) the last day of the two and one-half year period beginning on the enactment date [July 12, 1960] or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 [now 721] of the basic Act [this section]. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

''(b) Subject to the other provisions of this section—

''(1) any color additive which, on the day preceding the enactment date [July 12, 1960], was listed and certifiable for any use or uses under section 406(b), 504, or 604 [section 346(b), 354, or 364 of this title], or under the third proviso of section 402(c) [section 342(c) of this title], of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date [July 12, 1960], and

''(2) any color additive which was commercially used or sold prior to the enactment date [July 12, 1960] for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date [July 12, 1960], was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date [July 12, 1960], be deemed to be provisionally listed under this section as a color additive for such use or uses.

''(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act [section 346(b), 354, or 364 of this title] prior to the enactment

date [July 12, 1960], although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

''(d)(1) The Secretary shall, by regulations issued or amended from time to time under this section—

''(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

''(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

''(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 [now 721] of the basic Act [this section];

''(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b)(2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

''(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

''(2)(A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act [subsec. (e) of this section], but for the purposes of the application of section 706(e) [now 721(e)] of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706 [now 721, this section]. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date [July 12, 1960] were in effect pursuant to section 706 [now 721] of the basic Act [this section], shall be deemed to be regulations under such section 706 [now 721, this section] as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 [now 721] as in effect prior to the enactment date [July 12, 1960] shall be available for the purposes specified in such section 706 [now 721, this section] as so amended.

''(B) If the Secretary, by regulation—

''(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

''(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

''(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act [section 371(f) of this title] except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

''(D) On and after the enactment date [July 12, 1960], regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 [now 721] of the basic Act [this section]. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706(b) or (c) [now 721(b), (c)] of the basic Act [subsec. (b) or (c) of this section].

''(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1)(A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act [July 12, 1960], afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1)(A), or for determining the prevailing level or levels of use thereof prior to the enactment date [July 12, 1960] with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1)(C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

''SEC. 204. [EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS INSPECTION ACTS.] Nothing in this Act [amending this section and sections 321, 331, 333, 342, 343, 346, 351, 352, 361, 362, and 371 of this title and repealing sections 354 and 364 of this title] shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following) [see section 601 et seq. of

this title] or the Poultry Products Inspection Act (21 U.S.C. 451 and the following).''

EFFECTIVE DATE; ACCELERATION

This section was made ''immediately effective'' by act May 2, 1939, ch. 107, title I, § 1, 53 Stat. 631.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 343, 346a, 351, 352, 360j, 361, 362, 453, 601, 1033 of this title.

## PART C—FEES

### SUBPART 1—FREEDOM OF INFORMATION FEES

### § 379f. Recovery and retention of fees for freedom of information requests

**(a) In general**

The Secretary, acting through the Commissioner of Food and Drugs, may—

(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, to recover all reasonable costs incurred in processing requests made under section 552 of title 5 for records obtained or created under this chapter or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

(2) retain all fees charged for such requests; and

(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

**(b) Use of fees**

The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1) of this section. Such fees shall not be used to reduce the amount of funds made to carry out other provisions of this chapter.

**(c) Waiver of fees**

Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5.

(June 25, 1938, ch. 675, § 731, formerly § 711, as added Nov. 28, 1990, Pub. L. 101–635, title II, § 201, 104 Stat. 4584; renumbered § 731, Oct. 29, 1992, Pub. L. 102–571, title I, § 106(6), 106 Stat. 4499.)

CODIFICATION

Section was formerly classified to section 379c of this title prior to renumbering by Pub. L. 102–571.

### SUBPART 2—FEES RELATING TO DRUGS

### § 379g. Definitions

For purposes of this part:

(1) The term ''human drug application'' means an application for—

(A) approval of a new drug submitted under section 355(b)(1) of this title,

(B) approval of a new drug submitted under section 355(b)(2) of this title after September 30, 1992, which requests approval of—

(i) a molecular entity which is an active ingredient (including any salt or ester of an active ingredient), or

(ii) an indication for a use,

that had not been approved under an application submitted under section 355(b) of this title,

(C) initial certification or initial approval of an antibiotic drug under section 357 of this title, or

(D) licensure of a biological product under section 262 of title 42.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 262 of title 42, and does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992.

(2) The term ''supplement'' means a request to the Secretary to approve a change in a human drug application which has been approved.

(3) The term ''prescription drug product'' means a specific strength or potency of a drug in final dosage form—

(A) for which a human drug application has been approved, and

(B) which may be dispensed only under prescription pursuant to section 353(b) of this title.

Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 262 of title 42, and does not include a large volume parenteral drug product approved before September 1, 1992.

(4) The term ''final dosage form'' means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without further manufacturing.

(5) The term ''prescription drug establishment'' means a foreign or domestic place of business which is—

(A) at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more prescription drug products are manufactured in final dosage form, and

(B) under the management of a person that is listed as the applicant in a human drug application for a prescription drug product with respect to at least one such product.

For purposes of this paragraph, the term ''manufactured'' does not include packaging.

(6) The term ''process for the review of human drug applications'' means the following activities of the Secretary with respect to the review of human drug applications and supplements:

(A) The activities necessary for the review of human drug applications and supplements.

(B) The issuance of action letters which approve human drug applications or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary's review of pending human drug applications and supplements.

(D) Activities necessary for the review of applications for licensure of establishments subject to section 262 of title 42 and for the release of lots of biologics under such section.

(E) Monitoring of research conducted in connection with the review of human drug applications.

(7) The term ''costs of resources allocated for the process for the review of human drug applications'' means the expenses incurred in connection with the process for the review of human drug applications for—

(A) officers and employees of the Food and Drug Administration, employees under contract with the Food and Drug Administration who work in facilities owned or leased for the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees,

(B) management of information, and the acquisition, maintenance, and repair of computer resources,

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

(D) collecting fees under section 379h of this title and accounting for resources allocated for the review of human drug applications and supplements.

(8) The term ''adjustment factor'' applicable to a fiscal year is the lower of—

(A) the Consumer Price Index for all urban consumers (all items; United States city average) for August of the preceding fiscal year divided by such Index for August 1992, or

(B) the total of discretionary budget authority provided for programs in the domestic category for the immediately preceding fiscal year (as reported in the Office of Management and Budget sequestration preview report, if available, required under section 254(d) of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 904(d)]) divided by such budget authority for fiscal year 1992 (as reported in the Office of Management and Budget final sequestration report submitted after the end of the 102d Congress, 2d Session).

The terms ''budget authority'' and ''category'' in subparagraph (B) are as defined in the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.], as in effect as of September 1, 1992.

(June 25, 1938, ch. 675, § 735, as added Oct. 29, 1992, Pub. L. 102–571, title I, § 103, 106 Stat. 4491.)

TERMINATION OF SECTION

*For termination of section by section 105 of Pub. L. 102–571, see Termination Date note below.*

REFERENCES IN TEXT

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in par. (8), is title II of Pub. L. 99–177, Dec. 12, 1985, 99 Stat. 1038, as amended, which enacted chapter 20 (§ 900 et seq.) and sections 654 to 656 of Title 2, The Congress, amended sections 602, 622, 631 to 642, and 651 to 653 of Title 2, sections 1104 to 1106, and 1109 of Title 31, Money and Finance, and section 911 of Title 42, The Public Health and Welfare, repealed section 661 of Title 2, enacted provisions set out as notes under section 900 of Title 2 and section 911 of Title 42, and amended provisions set out as a note under section 621 of Title 2. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

TERMINATION DATE

Section 105 of Pub. L. 102–571 provided that: ''The amendments made by section 103 [enacting this subpart] shall not be in effect after October 1, 1997 and section 104 [enacting provisions set out as a note below] shall not be in effect after 120 days after such date.''

CONGRESSIONAL FINDINGS CONCERNING PRESCRIPTION DRUG USER FEES

Section 102 of title I of Pub. L. 102–571 provided that: ''The Congress finds that—

''(1) prompt approval of safe and effective new drugs is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

''(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications; and

''(3) the fees authorized by this title [see Short Title of 1992 Amendment note, set out under section 301 of this title] will be dedicated toward expediting the review of human drug applications as set forth in the goals identified in the letters of September 14, 1992, and September 21, 1992, from the Commissioner of Food and Drugs to the Chairman of the Energy and Commerce Committee of the House of Representatives and the Chairman of the Labor and Human Resources Committee of the Senate, as set forth at 138 Cong. Rec. H9099–H9100 (daily ed. September 22, 1992).''

ANNUAL REPORTS

Section 104 of Pub. L. 102–571 provided that:

''(a) FIRST REPORT.—Within 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], the Secretary of Health and Human Services shall submit a report stating the Food and Drug Administration's progress in achieving the goals identified in section 102(3) of this Act [set out as a note above] during such fiscal year and that agency's future plans for meeting such goals.

''(b) SECOND REPORT.—Within 120 days after the end of each fiscal year during which such fees are collected, the Secretary of Health and Human Services shall submit a report on the implementation of the authority for such fees during such fiscal year and on the use the Food and Drug Administration made of the fees collected during such fiscal year for which the report is made.

''(c) COMMITTEES.—The reports described in subsections (a) and (b) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.''

ANIMAL DRUG USER FEE STUDY

Section 108 of Pub. L. 102–571 provided that:

''(a) STUDY.—The Secretary, in consultation with manufacturers of animal drug products and other interested persons, shall undertake a study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds in order to improve the process of reviewing applications (including abbreviated and supplemental applications) for new animal drugs under section 512 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b]. The study shall include—

''(1) an assessment of the overall review process for animal drugs at the Center for Veterinary Medicine, including the number of applications received, and the average times for interim and final decisions on each type of application,

''(2) the current allocation of funds to the animal drug review process,

''(3) recommendations for goals for decision making times on applications submitted to the Center for Veterinary Medicine and for additional resources required to meet the goals, and

''(4) recommendations for supplementing the resources for the animal drug review process through user fees.

''(b) COMPLETION.—The results of the study required by subsection (a) shall be presented no later than January 4, 1994, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 379h of this title.

## § 379h. Authority to assess and use drug fees

### (a) Types of fees

Beginning in fiscal year 1993, the Secretary shall assess and collect fees in accordance with this section as follows:

#### (1) Human drug application and supplement fee

##### (A) In general

Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

(i) A fee established in subsection (b) of this section for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established in subsection (b) of this section for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required.

##### (B) Payment schedule

###### (i) First payment

50 percent of the fee required by subparagraph (A) shall be due upon submission of the application or supplement.

###### (ii) Final payment

The remaining 50 percent of the fee required by subparagraph (A) shall be due upon—

(I) the expiration of 30 days from the date the Secretary sends to the applicant a letter designated by the Secretary as an action letter described in section 379g(6)(B) of this title, or

(II) the withdrawal of the application or supplement after it is filed unless the Secretary waives the fee or a portion of the fee because no substantial work was performed on such application or supplement after it was filed.

The designation under subclause (I) or the waiver under subclause (II) shall be solely in the discretion of the Secretary and shall not be reviewable.

##### (C) Exception for previously filed application or supplement

If a human drug application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

##### (D) Refund of fee if application not accepted for filing

The Secretary shall refund 50 percent of the fee paid under subparagraph (B)(i) for any application or supplement which is not accepted for filing.

#### (2) Prescription drug establishment fee

Each person that—

(A) owns a prescription drug establishment, at which is manufactured at least 1 prescription drug product which is not the, or not the same as a, product approved under an application filed under section 355(b)(2) or 355(j) of this title, and

(B) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be subject to the annual fee established in subsection (b) of this section for each such establishment, payable on or before January 31 of each year.

**(3) Prescription drug product fee**

**(A) In general**

Except as provided in subparagraph (B), each person—

(i) who is named as the applicant in a human drug application for a prescription drug product which is listed under section 360 of this title, and

(ii) who, after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall pay for each such prescription drug product the annual fee established in subsection (b) of this section. Such fee shall be payable at the time of the first such listing of such product in each calendar year. Such fee shall be paid only once each year for each listed prescription drug product irrespective of the number of times such product is listed under section 360 of this title.

**(B) Exception**

The listing of a prescription drug product under section 360 of this title shall not require the person who listed such product to pay the fee prescribed by subparagraph (A) if such product is the same product as a product approved under an application filed under section 355(b)(2) or 355(j) of this title.

**(b) Fee amounts**

**(1) Schedule**

Except as provided in paragraph (2) and subsections (c), (d), (f), and (g) of this section, the fees required under subsection (a) of this section shall be paid in accordance with the following schedule:

| | Fiscal Year 1993 | Fiscal Year 1994 | Fiscal Year 1995 | Fiscal Year 1996 | Fiscal Year 1997 |
|---|---|---|---|---|---|
| Drug application fee: | | | | | |
| Subsection (a)(1)(A)(i) fee | $100,000 | $150,000 | $208,000 | $217,000 | $233,000 |
| Subsection (a)(1)(A)(ii) fee | $50,000 | $75,000 | $104,000 | $108,000 | $116,000 |
| Fee revenue | $12,000,000 | $18,000,000 | $25,000,000 | $26,000,000 | $28,000,000 |
| Annual establishment fee: | | | | | |
| Fee per establishment | $60,000 | $88,000 | $126,000 | $131,000 | $138,000 |
| Fee revenue | $12,000,000 | $18,000,000 | $25,000,000 | $26,000,000 | $28,000,000 |
| Annual product fee: | | | | | |
| Fee per product | $6,000 | $9,000 | $12,500 | $13,000 | $14,000 |
| Fee revenue | $12,000,000 | $18,000,000 | $25,000,000 | $26,000,000 | $28,000,000 |
| Total fee revenues | $36,000,000 | $54,000,000 | $75,000,000 | $78,000,000 | $84,000,000 |

**(2) Small business exception**

Any business which has fewer than 500 employees, including employees of affiliates, and which does not have a prescription drug product introduced or delivered for introduction into interstate commerce shall pay one-half the amount of the fee for human drug applications it submits and shall pay the entire amount of the fee for supplements it submits. Such a business shall not be required to pay any portion of any fee required under subsection (a)(1)(A) of this section until 1 year after the date of the submission of the application involved. For purposes of this paragraph, one business is an affiliate of another business when, directly or indirectly, one business controls, or has the power to control, the other business or a third party controls, or has the power to control, both businesses.

**(c) Increases and adjustments**

**(1) Revenue increase**

The total fee revenues established by the schedule in subsection (b)(1) of this section shall be increased by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage increase that occurred during the preceding fiscal year in the Consumer Price Index for all urban consumers (all items; U.S. city average), or

(B) the total percentage increase for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

**(2) Annual fee adjustment**

Subject to the amount appropriated for a fiscal year under subsection (g) of this section, the Secretary shall, within 60 days after the end of each fiscal year beginning after October 1, 1992, adjust the fees established by the schedule in subsection (b)(1) of this section for the following fiscal year to achieve the total fee revenues, as may be increased under paragraph (1). Such fees shall be adjusted under this paragraph to maintain the proportions established in such schedule.

**(3) Limit**

The total amount of fees charged, as adjusted under paragraph (2), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

**(d) Fee waiver or reduction**

The Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) of this section where the Secretary finds that—

(1) such waiver or reduction is necessary to protect the public health,

(2) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(3) the fees to be paid by such person will exceed the anticipated present and future costs

incurred by the Secretary in conducting the process for the review of human drug applications for such person, or

(4) assessment of the fee for an application or a supplement filed under section 355(b)(1) of this title pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 355(b)(2) of this title could not be assessed fees under subsection (a)(1) of this section.

In making the finding in paragraph (3), the Secretary may use standard costs.

**(e) Effect of failure to pay fees**

A human drug application or supplement submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

**(f) Assessment of fees**

**(1) Limitation**

Fees may not be assessed under subsection (a) of this section for a fiscal year beginning after fiscal year 1993 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1992 multiplied by the adjustment factor applicable to the fiscal year involved.

**(2) Authority**

If the Secretary does not assess fees under subsection (a) of this section during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug applications and supplements, prescription drug establishments, and prescription drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) of this section relating to the date fees are to be paid.

**(g) Crediting and availability of fees**

**(1) In general**

Fees collected for a fiscal year pursuant to subsection (a) of this section shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.

**(2) Collections and appropriation acts**

The fees authorized by this section—

(A) shall be collected in each fiscal year in an amount equal to the amount specified in appropriation Acts for such fiscal year, and

(B) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs for fiscal year 1992 multiplied by the adjustment factor.

**(3) Authorization of appropriations**

There are authorized to be appropriated for fees under this section—

(A) $36,000,000 for fiscal year 1993,
(B) $54,000,000 for fiscal year 1994,
(C) $75,000,000 for fiscal year 1995,
(D) $78,000,000 for fiscal year 1996, and
(E) $84,000,000 for fiscal year 1997,

as adjusted to reflect increases in the total fee revenues made under subsection (c)(1) of this section.

**(h) Collection of unpaid fees**

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) of this section within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

**(i) Construction**

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(June 25, 1938, ch. 675, § 736, as added Oct. 29, 1992, Pub. L. 102–571, title I, § 103, 106 Stat. 4494.)

TERMINATION OF SECTION

*For termination of section by section 105 of Pub. L. 102–571, see Termination Date note below.*

TERMINATION DATE

Section not in effect after Oct. 1, 1997, see section 105 of Pub. L. 102–571, set out as a note under section 379g of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 379g of this title.

## SUBCHAPTER VIII—IMPORTS AND EXPORTS

### § 381. Imports and exports

**(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission**

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 360 of this title

and shall request that if any drugs and devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs and devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph[1] shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

**(b) Disposition of refused articles**

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this chapter or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

**(c) Charges concerning refused articles**

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

**(d) Reimportation**

(1) Except as provided in paragraph (2), no drug subject to section 353(b) of this title which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

**(e) Exports**

(1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

This paragraph does not authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 360b of this title.

(2) Paragraph (1) does not apply to any device—

(A) which does not comply with an applicable requirement of section 360d or 360e of this title,

(B) which under section 360j(g) of this title is exempt from either such section, or

(C) which is a banned device under section 360f of this title,

unless, in addition to the requirements of paragraph (1), the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export.

(June 25, 1938, ch. 675, §801, 52 Stat. 1058; Oct. 18, 1949, ch. 696, §§1–3, 63 Stat. 882; Oct. 10, 1962, Pub. L. 87–781, title III, §306, 76 Stat. 796; July 13, 1968, Pub. L. 90–399, §106, 82 Stat. 353; Oct. 27, 1970, Pub. L. 91–513, title II, §701(h), 84 Stat. 1282; May 28, 1976, Pub. L. 94–295, §§3(f), 4(b)(3), 90 Stat. 578, 580; Apr. 22, 1988, Pub. L. 100–293, §3, 102 Stat. 96; June 16, 1992, Pub. L. 102–300, §6(b)(1), 106 Stat.

[1] So in original. Probably should be ''subsection''.

240; Aug. 26, 1992, Pub. L. 102–353, § 5, 106 Stat. 943; Aug. 13, 1993, Pub. L. 103–80, § 3(cc), (dd)(1), 107 Stat. 778, 779.)

REFERENCES IN TEXT

The Controlled Substances Import and Export Act, referred to in subsec. (a), is title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, as amended, which is classified principally to subchapter II (§ 951 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 951 of this title and Tables.

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–80, § 3(dd)(1), substituted ''Health and Human Services'' for ''Agriculture'' after ''Secretary of'' in two places in first sentence.

Subsec. (b). Pub. L. 103–80, § 3(cc), substituted ''Secretary of Health and Human Services'' for ''Administrator'' after ''If it appears to the'', ''Secretary'' for ''Administrator'' after ''provisions of this subsection, the'', ''Secretary's'' for ''Administrator's'' after ''as may be specified in the'', ''Department of Health and Human Services'' for ''Federal Security Agency'', and ''Secretary'' for ''Administrator'' after ''designated by the''.

1992—Subsecs. (a), (b). Pub. L. 102–300, which directed the substitution of ''Health and Human Services'' for ''Health, Education, and Welfare'' wherever appearing, was executed in second sentence of subsec. (a), but could not be executed in first sentence of subsec. (a) or in subsec. (b) because such words did not appear. See 1993 Amendment note above and Transfer of Functions note below.

Subsec. (d)(1). Pub. L. 102–353 substituted ''manufacturer of'' for ''person who manufactured''.

1988—Subsecs. (d), (e). Pub. L. 100–293 added subsec. (d) and redesignated former subsec. (d) as (e).

1976—Subsec. (a). Pub. L. 94–295, §§ 3(f)(2), 4(b)(3), expanded provisions requiring the Secretary of Health, Education, and Welfare to request that the Secretary of the Treasury deliver to the Secretary of Health, Education, and Welfare items imported or offered for import into the United States that were manufactured, prepared, propagated, compounded, or processed in nonregistered establishments by extending the provisions to include devices imported or offered for import, and, in cl. (1), inserted reference to devices which were manufactured, packed, stored, or installed using methods, facilities, or controls not conforming to the requirements of section 360j(f) of this title.

Subsec. (d). Pub. L. 94–295, § 3(f)(1), designated existing provisions as par. (1) and added par. (2).

1970—Subsec. (a). Pub. L. 91–513 substituted ''Clause (2) of the third sentence of this paragraph'' for ''This paragraph'' and ''the Controlled Substances Import and Export Act'' for ''section 173 of this title'' in last sentence.

1968—Subsec. (d). Pub. L. 90–399 provided that nothing in subsec. (d) shall authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 360b of this title.

1962—Subsec. (a). Pub. L. 87–781 inserted provisions requiring the Secretary of Health, Education, and Welfare to furnish the Secretary of the Treasury a list of establishments registered under section 360(i) of this title, and to request that samples of any drugs from any establishments not so registered be delivered to the Secretary of Health, Education, and Welfare, with notice of delivery to the consignee who may appear before the Secretary to testify.

1949—Subsec. (a). Act Oct. 18, 1949, § 1, inserted before period at end of second sentence '', except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury within ninety days of the notice of such refusal or within such additional time as may be permitted pursuant to such regulations''.

Subsec. (b). Act Oct. 18, 1949, § 2, provided for express statutory authority for the long-standing administrative practice of releasing imported articles that do not comply with the requirements of the law so that they may be relabeled or given appropriate treatment to bring them into compliance.

Subsec. (c). Act Oct. 18, 1949, § 3, charged all costs, including salaries and travel and subsistence expenses of officers and employees, against importers.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100–293, set out as a note under section 353 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (d) by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizure or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotic and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 334, 360, 371, 382 of this title; title 15 section 1456.

## § 382. Exports of certain unapproved products

### (a) Drugs intended for human or animal use which require approval or licensing

A drug (including a biological product) intended for human or animal use—

(1) which—

(A) requires approval by the Secretary under section 355 of this title or section 360b of this title, or

(B) requires licensing by the Secretary under section 262 of title 42 or by the Secretary of Agriculture under the Act of March 4, 1913 [21 U.S.C. 151 et seq.] (known as the Virus Serum Toxin Act),

before it may be introduced or delivered for introduction into interstate commerce to a country, and

(2) which does not have such approval or license, which is not exempt from such sections or Act, and which is introduced or delivered for introduction into interstate commerce to a country,

is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug is authorized under subsection (b) of this section.

**(b) Conditions for export; active pursuit of drug approval or licensing; application for export, contents, approval or disapproval; list of eligible countries for export; criteria for list change**

(1) A drug (including a biological product) may, upon approval of an application submitted under paragraph (3), be exported if—

(A) the drug contains the same active ingredient as a—

(i) new drug—

(I) which has an exemption under section 355(i) of this title, and

(II) for which approval is actively being pursued by the person who has the exemption,

(ii) biological product for human use—

(I) which has an exemption under section 355(i) of this title, and

(II) for which licensing of the biological product under section 262 of title 42 is actively being pursued by the person who has the exemption,

(iii) biological product for animal use—

(I) for which authority has been granted under the Virus-Serum Toxin Act [21 U.S.C. 151 et seq.] for the preparation of an experimental drug product, and

(II) for which the licensing of the biological product under such Act is actively being pursued by the person who has the authority, or

(iv) new animal drug—

(I) which has an exemption under section 360b(j) of this title, and

(II) for which approval is actively being pursued by the person who has the exemption,

(B) except as provided in paragraph (2), the drug is exported to a country which is listed under paragraph (4) and in which the drug is approved and has not been withdrawn from sale,

(C) an application for the drug under section 355 or 360b of this title, section 262 of title 42, or the Virus-Serum Toxin Act [21 U.S.C. 151 et seq.] has not been disapproved by an order of the Secretary under section 355(d) or 360b(d) of this title or section 262 of title 42 or by the Secretary of Agriculture in the case of an application under the Virus-Serum Toxin Act,

(D) the drug is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and is not adulterated under paragraph (a)(1), (a)(2)(A), (a)(3), (c), or (d) of section 351 of this title,

(E) the outside of the shipping package is labeled with the following statement: ''This drug may be sold or offered for sale only in the following countries: '', the blank space being filled with a list of the countries to which export of the drug is authorized under this subsection,

(F) the drug is not the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the manufacture of the drug in the United States for export to a country is contrary to the public health and safety of the United States,

(G) the requirements of subparagraphs (A) through (D) of section 381(d)(1) of this title have been met.

The Secretary shall determine that an applicant is actively pursuing the approval or licensing of a drug if the applicant has demonstrated that degree of attention and continuous directed effort as may reasonably be expected from, and are ordinarily exercised by, a person before approval or licensing of a drug, such as the preparation for and the conduct of preclinical or clinical investigations, the analysis of the results of such investigations, conferences on such investigations with government officials, and the preparation of an application of approval or licensing for the drug.

(2) The Secretary may permit the export of a drug under paragraph (1) to a country which is listed under paragraph (4) and in which the drug is not approved if the drug is exported to such country solely for the purpose of further export to a country listed in paragraph (4) in which the drug is approved.

(3)(A) Any person may apply to have a drug exported under paragraph (1). Such an application shall be filed at least 90 days before the date the applicant proposes to export the drug for which the application is submitted. Before the expiration of 10 days from the date of the submission of such an application, the Secretary shall publish a notice in the Federal Register which identifies the applicant under such application, the drug proposed to be exported under such application, and the country to which the drug is proposed to be exported.

(B) An application for the export of a drug shall—

(i) identify the drug to be exported,

(ii) list each country to which the drug is to be exported and list the persons in each such country to which the drug is to be exported,

(iii) contain a certification by the applicant that—

(I) the applicant will export the drug only to a country which is listed in paragraph (4) and in which the drug is approved unless the drug is authorized to be exported under paragraph (2) and will export only those quantities of the drug which may reasonably be sold in each country to which it is to be exported,

(II) the drug is approved by each country to which it is to be exported unless the drug is authorized to be exported under paragraph (2) and the drug has not been withdrawn from sale in such country,

(III) the drug meets the requirements of paragraph (1)(D),

(IV) the drug will be labeled in accordance with paragraph (1)(E), and

(V) the drug meets the requirements of paragraphs (1)(C) and (1)(G),

(iv) contain a certification by the holder of the exemption or authority for such drug described in paragraph (1)(A) that the holder will actively pursue the approval or licensing of the drug,

(v) identify the exemption or authority for an experimental drug product in effect for such drug under the laws referred to in paragraph (1)(A),

(vi) identify the establishments in which the drug is manufactured, and

(vii) include a written agreement from each importer to whom the drug is to be exported from the United States that such importer will not export the drug to a country which is not listed under paragraph (4) and will provide notice to the applicant of any knowledge of an export of the drug to such a country by any person and will maintain records of the drug wholesale distributors to which the drug is sold.

(C)(i) Before the expiration of 30 days after the date an application is submitted to the Secretary, the Secretary shall review the application to determine if the application meets the requirements of clauses (i), (ii), (iv), (v), (vi), and (vii) of subparagraph (B) and contains the certifications described in clauses (iii) (other than the certification required by clause (iii)(II)) and (iv). If the Secretary determines that the application meets such requirements and contains such certifications the Secretary shall conditionally approve the application. An application which is so conditionally approved shall be finally approved within 5 days of the submission of the certification required by clause (iii)(II).

(ii) If the Secretary proposes to disapprove an application, the Secretary shall provide the applicant with a written statement specifying—

(I) the deficiencies which the applicant must correct in order to enable the Secretary to approve the application, and

(II) that the applicant has 60 days after receiving the statement to correct such deficiencies.

(D) If the holder of an application approved under subparagraph (C) for the export of a drug intends to export such drug to a country listed in paragraph (4) which is not listed in such application, such holder shall submit an amendment to such application to the Secretary not later than 30 days before the date of the proposed export to such country identifying the country to which the holder intends to export such drug and containing information sufficient to show that the drug is approved by such country and has not been withdrawn from sale in such country. The Secretary shall approve or disapprove the export of such drug to such country within 15 days of the receipt of the notice required by this subparagraph.

(4)(A) The countries to which a drug may be exported under paragraph (1) are—

(i) Australia,

(ii) Austria,

(iii) Belgium,

(iv) Canada,

(v) Denmark,

(vi) Federal Republic of Germany,

(vii) Finland,

(viii) France,

(ix) Iceland,

(x) Ireland,

(xi) Italy,

(xii) Japan,

(xiii) Luxembourg,

(xiv) The Netherlands,

(xv) New Zealand,

(xvi) Norway,

(xvii) Portugal,

(xviii) Spain,

(xix) Sweden,

(xx) Switzerland, and

(xxi) The United Kingdom,

(B) Changes in the list contained in subparagraph (A) shall be based on the following criteria:

(i) Statutory or regulatory requirements which require the review of drugs for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs must be in accordance with the approval of the drug.

**(c) Report to Secretary by holder of approved application; events requiring report; annual report to Secretary on pursuit of approval of drug**

(1) The holder of an approved application under subsection (b) of this section authorizing the export of a drug shall report to the Secretary—

(A) any withdrawal of an approval of the drug by any country to which it has been exported,

(B) any withdrawal of the drug from sale in any such country,

(C) the withdrawal of an application by the holder under section 355 or 360b of this title, section 262 of title 42, or the Virus-Serum Toxin Act [21 U.S.C. 151 et seq.], and

(D) the receipt of any credible information indicating that the drug is being or may have been exported from a country listed under subsection (b)(4) of this section to a country which is not listed under such subsection.

The reporting of an event described in subparagraph (A), (B), or (C) shall be made within 15

days of the occurrence of the event and the reporting of the receipt of information under subparagraph (D) shall be made within 15 days of the receipt of such information.

(2) The holder of an approved application under subsection (b) of this section authorizing the export of a drug shall report annually to the Secretary after the date of the approval of the application of the actions taken by the holder in pursuit of the approval of such drug during the year reported on. Not later than 90 days from the date of the receipt of a report under this paragraph the Secretary shall determine if the holder is actively pursuing the approval of such drug.

**(d) Export of drug under approved application prohibited**

A drug authorized to be exported to a country under an application approved under subsection (b) of this section may not be exported to such country if—

(1) an approval of such drug is withdrawn by such country,

(2) the drug is withdrawn from sale in such country,

(3) the Secretary issues an order refusing to approve an application of the holder of such application under section 355 or 360b of this title, section 262 of title 42, or the Virus-Serum Toxin Act [21 U.S.C. 151 et seq.], or

(4) an application for such drug under such section or Act is withdrawn or if an exemption for such drug under section 355(i) or 360b(j) of this title or the authority granted for such drug to prepare an experimental drug product under the Virus-Serum Toxin Act [21 U.S.C. 151 et seq.] is withdrawn and no application for approval of such drug has been submitted under section 355 or 360b of this title, section 262 of title 42, or the Virus-Serum Toxin Act.

**(e) Determination by Secretary of noncompliance, failure of active pursuit of drug approval, imminent hazard of drug to public health, or exportation of drug to noneligible country; notices and hearings; prohibition on exportation of drug**

(1) If the Secretary determines that—

(A) a drug for which an application was approved under subsection (b) of this section no longer complies with subparagraphs (A), (D), (E), and (G) of paragraph (1) of such subsection or with paragraph (2) of such subsection or the holder of such application has not made the reports required by subsection (c) of this section, or

(B) the manufacture of a drug in the United States for export is contrary to the public health and safety of the United States and an application for the export of such drug has been approved under subsection (b) of this section,

then before taking action against the holder of an application for which a determination was made under subparagraph (A) or (B), the Secretary shall notify the holder in writing of the determination and provide the holder 30 days to take such action as may be required so that the Secretary would be unable to make such determination. When the Secretary takes action against such holder because of such a determination, the Secretary shall provide the holder a written statement specifying the reasons for such determination and provide the person, on request, an opportunity for an informal hearing with respect to such determination.

(2) If the Secretary determines that the approval of a drug is not being actively pursued as required by subsection (b)(1)(A) of this section, the Secretary shall give the holder of the application authorizing the export of such drug 60 days to assure that actions are taken to actively pursue such approval. During the 60-day period the Secretary shall give the holder an opportunity for an informal hearing on the determination of the Secretary. If upon the expiration of such 60-day period the Secretary determines that approval of such drug is not being actively pursued, the Secretary shall prohibit the export of such drug.

(3)(A) If at any time the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that—

(i) the holder of an approved application under subsection (b) of this section is exporting a drug from the United States to an importer,

(ii) such importer is exporting the drug to a country which is not listed under subsection (b)(4) of this section, and

(iii) such export presents an imminent hazard to the public health in such country,

the Secretary shall immediately prohibit the export of the drug to such importer, give the person exporting the drug from the United States prompt notice of the determination, and afford such person an opportunity for an expedited hearing.

(B) The authority conferred by subparagraph (A) shall not be delegated by the Secretary. A determination by the Secretary under subparagraph (A) may not be stayed pending final action by a reviewing court.

(4)(A) If the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that the holder of an approved application under subsection (b) of this section is exporting a drug to a country which is not listed under subsection (b)(4) of this section and that the export of the drug presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug to such country, give the holder prompt notice of the determination, and afford the holder an opportunity for an expedited hearing.

(B) The authority conferred by subparagraph (A) shall not be delegated by the Secretary. A determination by the Secretary under subparagraph (A) may not be stayed pending final action by a reviewing court.

(5) If the Secretary receives credible evidence that the holder of an application approved under subsection (b) of this section is exporting a drug to a country which is not listed under subsection (b)(4) of this section, the Secretary shall give the holder 60 days to provide information to the Secretary respecting such evidence and shall provide the holder an opportunity for an informal hearing on such evidence. Upon the expiration of such 60 days the Secretary shall prohibit the export of such drug to such country if the

Secretary determines that the holder of the application is exporting the drug to a country which is not listed under subsection (b)(4) of this section.

(6) If the Secretary receives credible evidence that an importer is exporting a drug to a country which is not listed under subsection (b)(4) of this section, the Secretary shall notify the holder of the application authorizing the export of such drug of such evidence and shall require the holder to investigate the export by such importer and to report to the Secretary within 14 days of the receipt of such notice the findings of the holder. If the Secretary determines that the importer has exported a drug to such a country, the Secretary shall prohibit such holder from exporting such drug to the importer unless the Secretary determines that the export by the importer was unintentional.

**(f) Drugs used in prevention or treatment of tropical disease**

(1) A drug (including a biological product) which is to be used in the prevention or treatment of a tropical disease may, upon approval of an application submitted under paragraph (2), be exported if—

(A) the Secretary finds, based on credible scientific evidence, including clinical investigations, that the drug is safe and effective in the country to which it is to be exported in the prevention or treatment of a tropical disease in such country,

(B) the drug is manufactured, processed, packaged, and held in conformity with current good manufacturing practice and is not adulterated under paragraph (a)(1), (a)(2)(A), (a)(3), (c), or (d) of section 351 of this title,

(C) the outside of the shipping package is labeled with the following statement: ''This drug may be sold or offered for sale only in the following countries: '', the blank space being filled with a list of the countries to which export of the drug is authorized under this subsection,

(D) the drug is not the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the manufacture of the drug in the United States for export to a country is contrary to the public health and safety of the United States, and

(E) the requirements of subparagraphs (A) through (D) of section 381(d)(1) of this title have been met.

(2) Any person may apply to have a drug exported under paragraph (1). The application shall—

(A) describe the drug to be exported,

(B) list each country to which the drug is to be exported,

(C) contain a certification by the applicant that the drug will not be exported to a country for which the Secretary cannot make a finding described in paragraph (1)(A),

(D) identify the establishments in which the drug is manufactured, and

(E) demonstrate to the Secretary that the drug meets the requirements of paragraph (1).

(3) The holder of an approved application for the export of a drug under this subsection shall report to the Secretary—

(A) the receipt of any information indicating that the drug is being or may have been exported from a country for which the Secretary made a finding under paragraph (1)(A) to a country for which the Secretary cannot make such a finding, and

(B) the receipt of any information indicating any adverse reactions to such drug.

(4)(A) If the Secretary determines that—

(i) a drug for which an application is approved under paragraph (2) does not continue to meet the requirements of paragraph (1),

(ii) the holder of such application has not made the report required by paragraph (3), or

(iii) the manufacture of such drug in the United States for export is contrary to the public health and safety of the United States and an application for the export of such drug has been approved under paragraph (2),

then before taking action against the holder of an application for which a determination was made under clause (i), (ii), or (iii), the Secretary shall notify the holder in writing of the determination and provide the holder 30 days to take such action as may be required so that the Secretary would be unable to make such determination. When the Secretary takes action against such holder because of such a determination, the Secretary shall provide the holder a written statement specifying the reasons for such determination and provide the person, on request, an opportunity for an informal hearing with respect to such determination.

(B) If at any time the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that—

(i) the holder of an approved application under paragraph (2) is exporting a drug from the United States to an importer,

(ii) such importer is exporting the drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), and

(iii) such export presents an imminent hazard to the public health in such country,

the Secretary shall immediately prohibit the export of the drug to such importer, give the person exporting the drug from the United States prompt notice of the determination, and afford such person an opportunity for an expedited hearing. A determination by the Secretary under this subparagraph may not be stayed pending final action by a reviewing court. The authority conferred by this subparagraph shall not be delegated by the Secretary.

(C) If the Secretary, or in the absence of the Secretary the individual acting as the Secretary, determines that the holder of an approved application under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), and that the export of the drug presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug to such country, give the holder prompt notice of the determination, and afford the holder an opportunity for an expedited hearing. A determination by the Secretary under this subparagraph may not be stayed pending final action by a reviewing court. The authority conferred by this subparagraph shall not be delegated by the Secretary.

(D) If the Secretary receives credible evidence that the holder of an application approved under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), the Secretary shall give the holder 60 days to provide information to the Secretary respecting such evidence and shall provide the holder an opportunity for an informal hearing on such evidence. Upon the expiration of such 60 days the Secretary shall prohibit the export of such drug to such country if the Secretary determines the holder is exporting the drug to a country for which the Secretary cannot make a finding under paragraph (1)(A).

(E) If the Secretary receives credible evidence that an importer is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), the Secretary shall notify the holder of the application authorizing the export of such drug of such evidence and shall require the holder to investigate the export by such importer and to report to the Secretary within 14 days of the receipt of such notice the findings of the holder. If the Secretary determines that the importer has exported a drug to such a country, the Secretary shall prohibit such holder from exporting such drug to the importer unless the Secretary determines that the export by the importer was unintentional.

**(g) Reference to Secretary and holder of application**

For purposes of this section—

(1) a reference to the Secretary shall in the case of a biological product which is required to be licensed under the Virus-Serum Toxin Act [21 U.S.C. 151 et seq.] be considered to be a reference to the Secretary of Agriculture, and

(2) a reference in paragraph (3), (4), (5), or (6) of subsection (e) of this section and in subparagraph (B), (C), (D), or (E) of subsection (f)(4) of this section to the holder of an application shall be considered a reference to any person which is under common control with holder, is controlled by the holder, controls the holder, is owned by the holder, or owns the holder.

(June 25, 1938, ch. 675, § 802, as added Nov. 14, 1986, Pub. L. 99–660, title I, § 102(2), 100 Stat. 3743.)

REFERENCES IN TEXT

Act of March 4, 1913 (known as the Virus Serum Toxin Act), referred to in subsecs. (a)(1)(B), (b)(1)(A)(iii)(I), (C), (c)(1)(C), (d)(3), (4), and (g)(1), is act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended, which is classified generally to chapter 5 (§ 151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 151 of this title and Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title; title 42 section 262.

## § 383. Office of International Relations

(a) There is established in the Department of Health and Human Services an Office of International Relations.

(b) In carrying out the functions of the office under subsection (a) of this section, the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 360j(f) of this title, and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

(June 25, 1938, ch. 675, § 803, as added Nov. 28, 1990, Pub. L. 101–629, § 15(a), 104 Stat. 4525.)

REPORT ON ACTIVITIES OF OFFICE OF INTERNATIONAL RELATIONS

Section 15(b) of Pub. L. 101–629 directed Secretary of Health and Human Services, not later than 2 years after Nov. 28, 1990, to prepare and submit to the appropriate committees of Congress a report on the activities of the Office of International Relations under 21 U.S.C. 383.

# SUBCHAPTER IX—MISCELLANEOUS

## § 391. Separability clause

If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby.

(June 25, 1938, ch. 675, § 901, 52 Stat. 1059.)

## § 392. Exemption of meats and meat food products

**(a) Law determinative of exemption**

Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended [21 U.S.C. 601 et seq.].

**(b) Laws unaffected**

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of Public Health Service Act [42 U.S.C. 262] (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 [21 U.S.C. 151 et seq.]; the Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 [21 U.S.C. 61 et seq.]; or the Import Milk Act of February 15, 1927 [21 U.S.C. 141 et seq.].

(June 25, 1938, ch. 675, § 902(b), (c), 52 Stat. 1059; July 13, 1968, Pub. L. 90–399, § 107, 82 Stat. 353.)

REFERENCES IN TEXT

The Meat Inspection Act, approved March 4, 1907, as amended, referred to in subsec. (a), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90–201, 81 Stat. 584, which are classified generally to subchapters I to IV (§ 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

Act of March 4, 1913, referred to in subsec. (b), is act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended. The provisions of such act relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are classified generally to chapter 5 (§ 151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 151 of this title and Tables.

The Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), referred to in subsec. (b), is act June 6, 1896, ch. 337, 29 Stat. 253, as amended, which had been classified to chapter 10 (§ 1000 et seq.) of Title 26, Internal Revenue, and included as chapter 17 (§ 2350 et seq.) of Title 26, Internal Revenue Code of 1939. Such chapter 17 was covered by section 4831 et seq. of Title 26, Internal Revenue Code, prior to the repeal of section 4831 et seq. of Title 26 by Pub. L. 93–490, § 3(a)(1), Oct. 26, 1974, 88 Stat. 1466.

The Filled Milk Act of March 4, 1923, referred to in subsec. (b), is act Mar. 4, 1923, ch. 262, 42 Stat. 1486, as amended, which is classified generally to chapter 3 (§ 61 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 61 of this title and Tables.

The Import Milk Act of February 15, 1927, referred to in subsec. (b), is act Feb. 15, 1927, ch. 155, 44 Stat. 1101, as amended, which is classified generally to subchapter IV (§ 141 et seq.) of chapter 4 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 141 of this title and Tables.

CODIFICATION

Subsecs. (a) and (b) of this section comprise respectively subsecs. (b) and (c) of section 902 of act June 25, 1938. Subsecs. (a) and (d) of section 902 of act June 25, 1938, which prescribed the effective date of this chapter and made appropriations available, are set out as notes under section 301 of this title and this section, respectively.

AMENDMENTS

1968—Subsec. (b). Pub. L. 90–399 substituted ''section 262 of title 42 (relating to viruses, serums, toxins, and analogous products applicable to man)'' for ''the virus serum, and toxin Act of July 1, 1902'' and inserted reference to ''the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913''.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

AVAILABILITY OF APPROPRIATIONS

Section 902(d) of act June 25, 1938, provided that: ''In order to carry out the provisions of this Act which take effect [see section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title] prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended [sections 1 to 15 of this title], appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 679 of this title.

## § 393. Food and Drug Administration

### (a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the ''Administration'').

### (b) Commissioner

#### (1) Appointment

There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the ''Commissioner'') who shall be appointed by the President by and with the advice and consent of the Senate.

#### (2) General powers

The Secretary, through the Commissioner, shall be responsible for executing this chapter and for—

(A) providing overall direction to the Food and Drug Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration;

(B) coordinating and overseeing the operation of all administrative entities within the Administration;

(C) research relating to foods, drugs, cosmetics, and devices in carrying out this chapter;

(D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and

(E) performing such other functions as the Secretary may prescribe.

### (c) Technical and scientific review groups

The Secretary through the Commissioner of Food and Drugs may, without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under this chapter, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(June 25, 1938, ch. 675, § 903, as added Nov. 4, 1988, Pub. L. 100–607, title V, § 503(a), 102 Stat. 3121; amended Nov. 18, 1988, Pub. L. 100–690, title II, § 2631, 102 Stat. 4244.)

REFERENCES IN TEXT

The provisions of title 5 governing appointments in the competitive service, referred to in subsec. (c), are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

CODIFICATION

Another section 903 of the Federal Food, Drug, and Cosmetic Act was renumbered section 904 and is classified to section 394 of this title.

AMENDMENTS

1988—Subsec. (b)(2). Pub. L. 100–690 substituted ''shall be responsible for executing this chapter and for ''shall be responsible''.

EFFECTIVE DATE

Section 503(c) of title V of Pub. L. 100–607 provided that:

''(1) Except as provided in paragraph (2), the amendments made by this title [enacting this section and amending sections 5315 and 5316 of Title 5, Government Organization and Employees] shall take effect on the date of enactment of this Act [Nov. 4, 1988].

''(2) Section 903(b)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 393(b)(1)] (as added by subsection (a) of this section) shall apply to the appointments of Commissioners of Food and Drugs made after the date of enactment of this Act.''

MANAGEMENT ACTIVITIES STUDY

Pub. L. 102–571, title II, § 205, Oct. 29, 1992, 106 Stat. 4502, directed Comptroller General to conduct a study of management of activities of the Food and Drug Administration that are related to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances and submit an interim report to Congress, not later than 6 months after Oct. 29, 1992, with a final report to be submitted not later than 12 months after Oct. 29, 1992.

CONGRESSIONAL FINDINGS

Section 502 of Pub. L. 100–607 provided that: ''Congress finds that—

''(1) the public health has been effectively protected by the presence of the Food and Drug Administration during the last eighty years;

''(2) the presence and importance of the Food and Drug Administration must be guaranteed; and

''(3) the independence and integrity of the Food and Drug Administration need to be enhanced in order to ensure the continuing protection of the public health.''

### § 394. Scientific review groups

Without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this chapter); and

(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(June 25, 1938, ch. 675, § 904, formerly § 903, as added Nov. 28, 1990, Pub. L. 101–635, title III, § 301, 104 Stat. 4584; renumbered § 904, June 10, 1993, Pub. L. 103–43, title XX, § 2006(1), 107 Stat. 209.)

REFERENCES IN TEXT

The provisions of title 5 governing appointments in the competitive service, referred to in text, are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

### § 395. Loan repayment program

**(a) In general**

**(1) Authority for program**

Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the Food and Drug Administration, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $20,000 of the principal and interest of the educational loans of such health professionals.

**(2) Limitation**

The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the Food and Drug Administration for purposes of paragraph (1) for a period of not less than 3 years.

**(b) Applicability of certain provisions**

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III of the Public Health Service Act [42 U.S.C. 254*l* et seq.], the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

**(c) Authorization of appropriations**

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(June 25, 1938, ch. 675, § 905, as added June 10, 1993, Pub. L. 103–43, title XX, § 2006(2), 107 Stat. 210.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended. Subpart III of part D of title III of the Act is classified generally to subpart III [§ 254*l* et seq.] of part D of subchapter II of chapter 6A of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

## CHAPTER 10—POULTRY AND POULTRY PRODUCTS INSPECTION

Sec.
451. Congressional statement of findings.
452. Congressional declaration of policy.
453. Definitions.
454. Federal and State cooperation in development and administration of State poultry product inspection programs.
(a) State laws; planning, technical and financial assistance; advisory committees.
(b) Appropriate State agency; performance of functions by subordinate governmental unit.
(c) Intrastate activities; designation of State for regulation; publication of designation; exempted operations; termination of designation; review of operations in nondesignated States; annual report.
(d) ''State'' defined.
455. Inspection in official establishments.
(a) Ante mortem inspection.
(b) Post mortem inspection; quarantine, segregation, and reinspection.
(c) Condemnation; appeal; reprocessing.
456. Operation of premises, facilities and equipment.

Sec.
(a) Sanitary practices.
(b) Refusal of inspection.
457. Labeling and container standards.
(a) Requirements for shipping containers and immediate containers; nonconsumer packaged carcasses.
(b) Labeling requirements; definitions and standards of identity or composition or articles and standards of fill of container; standards consistent with Federal Food, Drug, and Cosmetic Act; consistency between Federal and State standards.
(c) Use of trade names; false or misleading marking or labeling; misleading form or size of container.
(d) Withholding use of false or misleading mark, label, or container size or form; modification; hearing; conclusiveness of determination; appeal.
458. Prohibited acts.
459. Compliance by all establishments.
460. Miscellaneous activities subject to regulation.
(a) Prohibition of inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles.
(b) Recordkeeping requirements; persons liable; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples.
(c) Registration of business, name of person, and trade names.
(d) Regulation of transactions, transportation, or importation of dead, dying, disabled or diseased poultry or carcasses to prevent use as human food.
(e) Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority.
461. Offenses and punishment.
(a) Violations; liability of agents, employees, and employers.
(b) Liability of carrier.
(c) Assaulting, resisting, or impeding certain persons; murder; punishments.
462. Reporting of violations; notice; opportunity to present views.
463. Rules and regulations.
(a) Storage and handling of poultry products; violation of regulations.
(b) Other necessary rules and regulations.
(c) Oral presentation of views.
464. Exemptions.
(a) Persons exempted.
(b) Territorial exemption.
(c) Personal slaughtering; custom slaughtering; name and address of the poultry producer or processor in lieu of other labeling requirements; small enterprises; slaughterers or processors of specified number of turkeys; poultry producers raising poultry on own farms.
(d) Pizzas containing poultry products.
(e) Applicability of adulteration and misbranding provisions to articles exempted from inspection.
(f) Suspension or termination of exemption.
465. Limitations upon entry of poultry products and other materials into official establishments.
Sec.
466. Imports.
(a) Compliance with standards and regulations; status after importation.
(b) Rules and regulations; destruction and exportation of refused imports.
(c) Storage, cartage and labor charges for imports refused admission.
(d) Domestic standards and processing facilities applicable; enforcement.
467. Inspection services.
(a) Refusal or withdrawal; hearing; business unfitness based upon certain convictions; persons responsibly connected with the business.
(b) Hearing to determine validity of withdrawal or refusal of inspection services; continuation of withdrawal or refusal.
(c) Finality and conclusiveness of determination; judicial review; record.
467a. Administrative detention; duration; pending judicial proceedings; notification of government authorities; release; removal of official marks.
467b. Seizure and condemnation.
(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bonds; court costs and fees, storage, and other expenses against claimants; jury trial; United States as plaintiff.
(b) Condemnation or seizure under other provisions unaffected.
467c. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations; United States as plaintiff; subpenas.
467d. Administration and enforcement; applicability of penalty provisions; conduct of inquiries; power and jurisdiction of courts.
467e. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters.
467f. Federal Food, Drug, and Cosmetic Act applications.
(a) Exemptions; authorities under food, drug, and cosmetic provisions unaffected.
(b) Enforcement proceedings; detainer authority of representatives of Secretary of Health and Human Services.
468. Cost of inspection; overtime.
469. Authorization of appropriations.
470. Reports to Congress.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 321 of this title; title 7 sections 138f, 6519.

## § 451. Congressional statement of findings

Poultry and poultry products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry prod-

ucts distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded poultry products impair the effective regulation of poultry products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers. It is hereby found that all articles and poultry which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

(Pub. L. 85–172, § 2, Aug. 28, 1957, 71 Stat. 441; Pub. L. 90–492, § 2, Aug. 18, 1968, 82 Stat. 791.)

AMENDMENTS

1968—Pub. L. 90–492 inserted provisions stating it to be necessary that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged, provisions that misbranded poultry products impair the effective regulation of poultry products and destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers, and provisions that all articles and poultry which are regulated by this chapter are either in interstate or foreign commerce or substantially affect such commerce and that regulation by the Secretary of Agriculture and cooperation by the states and other jurisdictions as contemplated by this chapter are appropriate to serve the specified aims, and struck out provisions that all poultry and poultry products which have or are required to have inspection under this chapter are either in the current of interstate or foreign commerce or directly affect such commerce, provisions that that part entering directly into the current of interstate or foreign commerce cannot be effectively inspected and regulated without also inspecting and regulating all poultry and poultry products in the same establishment, and provisions authorizing the Secretary to designate major consuming areas.

EFFECTIVE DATE OF 1968 AMENDMENT

Section 20 of Pub. L. 90–492 provided that: ''This Act [see Short Title of 1968 Amendment note below] shall become effective upon enactment [Aug. 18, 1968] except as provided in paragraphs (a) through (c):

''(a) The provisions of subparagraphs (a)(2)(A) and (a)(3) of section 9 of the Poultry Products Inspection Act, as amended by section 9 of this Act [section 458(a)(2)(A) and (a)(3) of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968].

''(b) Section 14 of this Act, amending section 15 of the Poultry Products Inspection Act [section 464 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968].

''(c) Paragraph 11(d) of the Poultry Products Inspection Act, as added by section 11 of this Act [section 460(d) of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968].''

EFFECTIVE DATE

Section 29, formerly section 22, of Pub. L. 85–172, as renumbered by Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 805, provided that: ''This Act [this chapter] shall take effect upon enactment [Aug. 28, 1957], except that no person shall be subject to the provisions of this Act [this chapter] prior to January 1, 1959, unless such person after January 1, 1958, applies for and receives inspection for poultry or poultry products in accordance with the provisions of this Act [this chapter] and pursuant to regulations promulgated by the Secretary hereunder, in any establishment processing poultry or poultry products in commerce or in a designated major consuming area. Any person who voluntarily applies for and receives such inspection after January 1, 1958, shall be subject, on and after the date he commences to receive such inspection, to all of the provisions and penalties provided for in this Act [this chapter] with respect to all poultry or poultry products handled in the establishment for which such said application for inspection is made.''

SHORT TITLE OF 1968 AMENDMENT

Section 1 of Pub. L. 90–492 provided: ''That this Act [enacting sections 467a to 467f and 470 of this title, amending this section and sections 452 to 461, 463 to 465, and 467 of this title, and enacting provisions set out as notes under this section] may be cited as the 'Wholesome Poultry Products Act'.''

SHORT TITLE

Section 1 of Pub. L. 85–172 provided: ''That this Act [enacting this chapter and provisions set out as notes under this section] may be cited as the 'Poultry Products Inspection Act'.''

SEPARABILITY

Section 19 of Pub. L. 90–492 provided that: ''If any provisions of this Act or of the amendments made hereby [see Short Title of 1968 Amendment note above] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act and the remaining amendments and of the application of such provision to other persons and circumstances shall not be affected thereby.''

Section 28, formerly section 21, of Pub. L. 85–172, as renumbered by Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 805, provided that: ''If any provision of this Act [this chapter] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act and of the application of such provision to other persons and circumstances shall not be affected thereby.''

FOOD ADDITIVES AMENDMENT OF 1958

Pub. L. 85–929, § 7, Sept. 6, 1958, 72 Stat. 1789, provided that: ''Nothing in this Act [amending sections 321, 331, 342, 346, and 348 of this title and section 210 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 321 and 342 of this title] shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act (21 U.S.C. 451 and the following) [this chapter] or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U.S.C. 71 and the following) [see section 601 et seq. of this title].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 454 of this title.

ACT REFERRED TO IN OTHER SECTIONS

The Wholesome Poultry Products Act is referred to in section 1053 of this title.

## § 452. Congressional declaration of policy

It is hereby declared to be the policy of the Congress to provide for the inspection of poultry

and poultry products and otherwise regulate the processing and distribution of such articles as hereinafter prescribed to prevent the movement or sale in interstate or foreign commerce of, or the burdening of such commerce by, poultry products which are adulterated or misbranded. It is the intent of Congress that when poultry and poultry products are condemned because of disease, the reason for condemnation in such instances shall be supported by scientific fact, information, or criteria, and such condemnation under this chapter shall be achieved through uniform inspection standards and uniform applications thereof.

(Pub. L. 85–172, § 3, Aug. 28, 1957, 71 Stat. 441; Pub. L. 90–492, § 3, Aug. 18, 1968, 82 Stat. 792.)

AMENDMENTS

1968—Pub. L. 90–492 inserted provisions declaring the policy of Congress to be to otherwise regulate the processing and distribution of poultry and poultry products as hereinafter prescribed so as to prevent the movement or sale in interstate commerce of, or the burdening of such commerce by poultry products which are adulterated or misbranded, and provisions that declared the policy of Congress to be that condemnation of diseased poultry and poultry products shall be achieved through uniform inspection standards and supported by scientific fact or criteria, and struck out provisions that declared the policy of Congress to be to provide for inspection by the inspection service to prevent the movement in interstate commerce or foreign commerce or in a designated major consuming area of poultry products which are unwholesome, adulterated, or otherwise unfit for human food.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

## § 453. Definitions

For purposes of this chapter—

(a) The term ''commerce'' means commerce between any State, any territory, or the District of Columbia, and any place outside thereof; or within any territory not organized with a legislative body, or the District of Columbia.

(b) Except as otherwise provided in this chapter, the term ''State'' means any State of the United States and the Commonwealth of Puerto Rico.

(c) The term ''territory'' means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(d) The term ''United States'' means the States, the District of Columbia, and the territories of the United States.

(e) The term ''poultry'' means any domesticated bird, whether live or dead.

(f) The term ''poultry product'' means any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary from definition as a poultry product under such conditions as the Secretary may prescribe to assure that the poultry ingredients in such products are not adulterated and that such products are not represented as poultry products.

(g) The term ''adulterated'' shall apply to any poultry product under one or more of the following circumstances:

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(A) if it bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not otherwise deemed adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in official establishments;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of any poultry which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(h) The term ''misbranded'' shall apply to any poultry product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(4) if its container is so made, formed, or filled as to be misleading;

(5) unless it bears a label showing (A) the name and the place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the product in terms of weight, measure, or numerical count: *Provided*, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages or articles not in packages or other containers may be established by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 457 of this title unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 457 of this title, and it falls below the standard to fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) if it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(10) if it purports to be or is represented for special dietary uses unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative unless it bears labeling stating that fact: *Provided*, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or

(12) if it fails to bear on its containers, and in the case of nonconsumer packaged carcasses (if the Secretary so requires) directly thereon, as the Secretary may by regulations prescribe, the official inspection legend and official establishment number of the establishment where the article was processed, and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(i) The term ''Secretary'' means the Secretary of Agriculture or his delegate.

(j) The term ''person'' means any individual, partnership, corporation, association, or other business unit.

(k) The term ''inspector'' means: (1) an employee or official of the United States Government authorized by the Secretary to inspect poultry and poultry products under the authority of this chapter, or (2) any employee or official of the government of any State or territory or the District of Columbia authorized by the Secretary to inspect poultry and poultry products under authority of this chapter, under an agreement entered into between the Secretary and the appropriate State or other agency.

(*l*) The term ''official mark'' means the official inspection legend or any other symbol prescribed by regulation of the Secretary to identify the status of any article or poultry under this chapter.

(m) The term ''official inspection legend'' means any symbol prescribed by regulations of the Secretary showing that an article was inspected for wholesomeness in accordance with this chapter.

(n) The term ''official certificate'' means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(*o*) The term ''official device'' means any device prescribed or authorized by the Secretary for use in applying any official mark.

(p) The term ''official establishment'' means any establishment as determined by the Secretary at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained under the authority of this chapter.

(q) The term ''inspection service'' means the official Government service within the Department of Agriculture designated by the Secretary

as having the responsibility for carrying out the provisions of this chapter.

(r) The term ''container'' or ''package'' includes any box, can, tin, cloth, plastic, or other receptacle, wrapper, or cover.

(s) The term ''label'' means a display of written, printed, or graphic matter upon any article or the immediate container (not including packaged liners) of any article; and the term ''labeling'' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(t) The term ''shipping container'' means any container used or intended for use in packaging the product packed in an immediate container.

(u) The term ''immediate container'' includes any consumer package; or any other container in which poultry products, not consumer packaged, are packed.

(v) The term ''capable of use as human food'' shall apply to any carcass, or part or product of a carcass, of any poultry, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human foods, or it is naturally inedible by humans.

(w) The term ''processed'' means slaughtered, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed.

(x) The term ''Federal Food, Drug, and Cosmetic Act'' means the Act so entitled, approved June 25, 1938 (52 Stat. 1040) [21 U.S.C. 301 et seq.], and Acts amendatory thereof or supplementary thereto.

(y) The terms ''pesticide chemical,'' ''food additive'', ''color additive'', and ''raw agricultural commodity'' shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(z) The term ''poultry products broker'' means any person engaged in the business of buying or selling poultry products on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person.

(aa) The term ''renderer'' means any person engaged in the business of rendering carcasses, or parts or products of the carcasses, of poultry, except rendering conducted under inspection or exemption under this chapter.

(bb) The term ''animal food manufacturer'' means any person engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of poultry.

(Pub. L. 85–172, § 4, Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–571, title I, § 107(13), Oct. 29, 1992, 106 Stat. 4499.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in pars. (x) and (y), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

AMENDMENTS

1992—Subsec. (g)(2)(D). Pub. L. 102–571 substituted ''379e'' for ''376''.

1968—Pub. L. 90–492 inserted definitions of ''State'', ''territory'', ''United States'', ''misbranded'', ''official mark'', ''official inspection legend'', ''official certificate'', ''official device'', ''capable of use as human food'', ''processed'', ''Federal Food, Drug, and Cosmetic Act'', ''pesticide chemical'', ''poultry products broker'', ''renderer'', and ''animal food manufacturer'', revised definitions of ''commerce'', ''poultry'', ''poultry product'', ''adulterated'', ''Secretary'', ''inspector'', ''container'' or ''package'', ''label'', and ''immediate container'', reenacted without change definitions of ''person'', ''official establishment'', ''inspection service'', and ''shipping container'', and deleted definition of ''wholesome'', ''unwholesome'', and ''official inspection mark''.

1962—Par. (a). Pub. L. 87–498 struck out references to Territories or possessions, and inserted definition of ''State''.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in par. (h)(10) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 457, 461, 464, 467b of this title; title 15 sections 2052, 2602.

## § 454. Federal and State cooperation in development and administration of State poultry product inspection programs

### (a) State laws; planning, technical and financial assistance; advisory committees

It is the policy of the Congress to protect the consuming public from poultry products that are adulterated or misbranded and to assist in efforts by State and other government agencies to accomplish this objective. In furtherance of this policy—

(1) The Secretary is authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with the appropriate State agency in developing and administering a State poultry product inspection program in any State which has enacted a mandatory State poultry product inspection law that imposes ante mortem and post mortem inspection, reinspection and sanitation requirements that are at least equal to those under this chapter, with respect to all or certain classes of persons engaged in the State in slaughtering poultry or processing poultry products for use as human food solely for distribution within such State.

(2) The Secretary is further authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with appropriate State agencies in developing and administering State programs under State laws containing authorities at least equal to those provided in section 460 of this title; and to cooperate with other agencies of the United States in carrying out any provi-

sions of this chapter. In carrying out the provisions of this chapter, the Secretary may conduct such examinations, investigations, and inspections as he determines practicable through any officer or employee of any State or Territory or the District of Columbia commissioned by the Secretary for such purpose.

(3) Cooperation with State agencies under this section may include furnishing to the appropriate State agency (i) advisory assistance in planning and otherwise developing an adequate State program under the State law; and (ii) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other aid for administration of such a program. The amount to be contributed to any State by the Secretary under this section from Federal funds for any year shall not exceed 50 per centum of the estimated total cost of the cooperative program; and the Federal funds shall be allocated among the States desiring to cooperate on an equitable basis. Such cooperation and payment shall be contingent at all times upon the administration of the State program in a manner which the Secretary, in consultation with the appropriate advisory committee appointed under subparagraph (4), deems adequate to effectuate the purposes of this section.

(4) The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with him concerning State and Federal programs with respect to poultry product inspection and other matters within the scope of this chapter, including evaluating State programs for purposes of this chapter, and obtaining better coordination and more uniformity among the State programs and between the Federal and State programs and adequate protection of consumers.

**(b) Appropriate State agency; performance of functions by subordinate governmental unit**

The appropriate State agency with which the Secretary may cooperate under this chapter shall be a single agency in the State which is primarily responsible for the coordination of the State programs having objectives similar to those under this chapter. When the State program includes performance of certain functions by a municipality or other subordinate governmental unit, such unit shall be deemed to be a part of the State agency for purposes of this section.

**(c) Intrastate activities; designation of State for regulation; publication of designation; exempted operations; termination of designation; review of operations in nondesignated States; annual report**

(1) If the Secretary has reason to believe, by thirty days prior to the expiration of two years after August 18, 1968, that a State has failed to develop or is not enforcing, with respect to all establishments within its jurisdiction (except those that would be exempted from Federal inspection under subparagraph (2) of this paragraph (c)) at which poultry are slaughtered, or poultry products are processed for use as human food, solely for distribution within such State, and the products of such establishments, requirements at least equal to those imposed under sections 451 to 453, 455 to 459, 461 to 467d of this title, he shall promptly notify the Governor of the State of this fact. If the Secretary determines, after consultation with the Governor of the State, or representative selected by him, that such requirements have not been developed and activated, he shall promptly after the expiration of such two-year period designate such State as one in which the provisions of said sections of this chapter shall apply to operations and transactions wholly within such State: *Provided*, That if the Secretary has reason to believe that the State will activate such requirements within one additional year, he may delay such designation for said period, and not designate the State, if he determines at the end of the year that the State then has such requirements in effective operation. The Secretary shall publish any such designation in the Federal Register and, upon the expiration of thirty days after such publication, the provisions of said sections of this chapter shall apply to operations and transactions and to persons engaged therein in the State to the same extent and in the same manner as if such operations and transactions were conducted in or for commerce. However, notwithstanding any other provision of this section, if the Secretary determines that any establishment within a State is producing adulterated poultry products for distribution within such State which would clearly endanger the public health he shall notify the Governor of the State and the appropriate advisory committee provided for by subparagraph (a)(4) of this section of such fact for effective action under State or local law. If the State does not take action to prevent such endangering of the public health within a reasonable time after such notice, as determined by the Secretary, in light of the risk to public health, the Secretary may forthwith designate any such establishment as subject to the provisions of said sections of this chapter, and thereupon the establishment and operator thereof shall be subject to such provisions as though engaged in commerce until such time as the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under said sections.

(2) The provisions of this chapter requiring inspection of the slaughter of poultry and the processing of poultry products shall not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments if such establishment are subject to such inspection provisions only under this paragraph (c). For the purposes of this subparagraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares poultry products that are ready to eat when they leave such facility and are served in meals or as entrees only to customers at restaurants owned or operated by the same person

owning or operating such facility: *Provided*, That such facility shall be subject to the provisions of section 460(b) of this title: *Provided further*, That the facility may be subject to the inspection requirements of this chapter for as long as the Secretary deems necessary, if the Secretary determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its poultry products are rendered adulterated.

(3) Whenever the Secretary determines that any State designated under this paragraph (c) has developed and will enforce State poultry products inspection requirements at least equal to those imposed under the aforesaid sections of this chapter, with respect to the operations and transactions within such State which are regulated under subparagraph (1) of this paragraph (c), he shall terminate the designation of such State under this paragraph (c), but this shall not preclude the subsequent redesignation of the State at any time upon thirty days' notice to the Governor and publication in the Federal Register in accordance with this paragraph, and any State may be designated upon such notice and publication, at any time after the period specified in this paragraph whether or not the State has theretofore been designated, upon the Secretary determining that it is not effectively enforcing requirements at least equal to those imposed under said sections.

(4) The Secretary shall promptly upon August 18, 1968, and periodically thereafter, but at least annually, review the requirements, including the enforcement thereof, of the several States not designated under this paragraph (c), with respect to the slaughter, and the processing, storage, handling, and distribution of poultry products, and inspection of such operations, and annually report thereon to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate in the report required in section 470 of this title.

**(d) "State" defined**

As used in this section, the term ''State'' means any State (including the Commonwealth of Puerto Rico) or organized territory.

(Pub. L. 85–172, § 5, Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, § 5, Aug. 18, 1968, 82 Stat. 796; Pub. L. 98–487, § 2, Oct. 17, 1984, 98 Stat. 2264; Pub. L. 103–437, § 8(1), Nov. 2, 1994, 108 Stat. 4588.)

CODIFICATION

In par. (c)(1), (4), ''August 18, 1968'' substituted for ''enactment of the Wholesome Poultry Products Act''.

AMENDMENTS

1994—Subsec. (c)(4). Pub. L. 103–437 substituted ''Agriculture, Nutrition, and Forestry'' for ''Agriculture and Forestry''.

1984—Par. (c)(2). Pub. L. 98–487 inserted provisions relating to operations conducted at a restaurant central kitchen facility.

1968—Pub. L. 90–492 substituted provisions authorizing the Secretary to cooperate with the appropriate state agency in the development and administration of state poultry product inspection programs in those states having mandatory poultry product inspection laws and those states having laws at least equal to the provisions of section 460 of this title, provisions authorizing planning, technical and financial assistance and the appointment of advisory committees, provisions designating the appropriate state agency with which the Secretary may cooperate, provisions authorizing the Secretary to designate states as subject to the regulatory provisions of this chapter when the requirements of the specified section have not been complied with or when the specified intrastate activities are present, provisions exempting from the requirements of this chapter operations of the types traditionally and usually conducted at retail stores and restaurants, provisions authorizing the Secretary to terminate the aforementioned designation of states as subject to the regulatory provisions of this chapter, and provisions authorizing the Secretary to review the operations in nondesignated states and make an annual report thereon, for provisions authorizing the Secretary, upon application by any appropriate state or local official or agency or by any appropriate local poultry industry group and after public hearing, to designate major consuming areas as subject to the regulatory provisions of this chapter where the Secretary finds that poultry or poultry products are handled or consumed in such volume as to affect, burden or obstruct the movement of inspected poultry products in interstate commerce.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 457, 460 of this title.

## § 455. Inspection in official establishments

**(a) Ante mortem inspection**

For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any poultry product which is capable of use as human food and is adulterated, the Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection of poultry in each official establishment processing poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

**(b) Post mortem inspection; quarantine, segregation, and reinspection**

The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post mortem inspection of the carcass of each bird processed, and at any time such quarantine, segregation, and reinspection as he deems necessary of poultry and poultry products capable of use as human food in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

**(c) Condemnation; appeal; reprocessing**

All poultry carcasses and parts thereof and other poultry products found to be adulterated shall be condemned and shall, if no appeal be taken from such determination of condemnation, be destroyed for human food purposes under the supervision of an inspector: *Provided*, That carcasses, parts, and products, which may by reprocessing be made not adulterated, need not be so condemned and destroyed if so reproc-

essed under the supervision of an inspector and thereafter found to be not adulterated. If an appeal be taken from such determination, the carcasses, parts, or products shall be appropriately marked and segregated pending completion of an appeal inspection, which appeal shall be at the cost of the appellant if the Secretary determines that the appeal is frivolous. If the determination of condemnation is sustained the carcasses, parts, and products shall be destroyed for human food purposes under the supervision of an inspector.

(Pub. L. 85–172, § 6, Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, § 6, Aug. 18, 1968, 82 Stat. 798.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492, § 6(a), substituted ''of, or the burdening of commerce by, any poultry product which is capable of use as human food and is adulterated,'' for ''or a designated major consuming area of any poultry product which is unwholesome or adulterated,'' ''each official establishment'' for ''any official establishment'', and ''otherwise subject to inspection under this chapter'' for ''in, or for marketing in a designated city or area''.

Par. (b). Pub. L. 90–492, § 6(b), substituted ''segregation, and reinspection'' for ''segregation, reinspection'', and ''otherwise subject to inspection under this chapter'' for ''in, or for marketing in a designated city or area'', and inserted ''capable of use as human food'' after ''necessary of poultry and poultry products''.

Par. (c). Pub. L. 90–492, § 6(c), inserted ''other'' before ''poultry products'', and substituted ''to be adulterated'' for ''to be unwholesome or adulterated'', ''made not adulterated'' for ''made not unwholesome and not adulterated'', and ''to be not adulterated'' for ''to be not unwholesome and not adulterated''.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467 of this title.

## § 456. Operation of premises, facilities and equipment

### (a) Sanitary practices

Each official establishment slaughtering poultry or processing poultry products for commerce or otherwise subject to inspection under this chapter shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce or burdensome effect upon commerce, of poultry products which are adulterated.

### (b) Refusal of inspection

The Secretary shall refuse to render inspection to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section.

(Pub. L. 85–172, § 7, Aug. 28, 1957, 71 Stat. 444; Pub. L. 90–492, § 7, Aug. 18, 1968, 82 Stat. 799.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492 substituted ''otherwise subject to inspection under this chapter'' for ''in or for marketing in a designated major consuming area'', ''burdensome effect upon commerce'' for ''in a designated major consuming area'', and ''which are adulterated'' for ''which are unwholesome or adulterated''.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467 of this title.

## § 457. Labeling and container standards

### (a) Requirements for shipping containers and immediate containers; nonconsumer packaged carcasses

All poultry products inspected at any official establishment under the authority of this chapter and found to be not adulterated, shall at the time they leave the establishment bear, in distinctly legible form, on their shipping containers and immediate containers as the Secretary may require, the information required under paragraph (h) of section 453 of this title. In addition, the Secretary whenever he determines such action is practicable and necessary for the protection of the public, may require nonconsumer packaged carcasses at the time they leave the establishment to bear directly thereon in distinctly legible form any information required under such paragraph (h).

### (b) Labeling requirements; definitions and standards of identity or composition or articles and standards of fill of container; standards consistent with Federal Food, Drug, and Cosmetic Act; consistency between Federal and State standards

The Secretary, whenever he determines such action is necessary for the protection of the public, may prescribe: (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling in marketing and labeling any articles or poultry subject to this chapter; (2) definitions and standards of identity or composition or articles subject to this chapter and standards of fill of container for such articles not inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and there shall be consultation between the Secretary and the Secretary of Health and Human Services prior to the issuance of such standards under either Act relating to articles subject to this chapter to avoid inconsistency in such standards and possible impairment of the coordinated effective administration of this chapter and the Federal Food, Drug, and Cosmetic Act. There shall also be consultation between the Secretary and an appropriate advisory committee provided for in section 454 of this title, prior to the issuance of such standards under this chapter, to avoid, insofar as feasible, inconsistency between Federal and State standards.

### (c) Use of trade names; false or misleading marking or labeling; misleading form or size of container

No article subject to this chapter shall be sold or offered for sale by any person in commerce,

under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.

**(d) Withholding use of false or misleading mark, label, or container size or form; modification; hearing; conclusiveness of determination; appeal**

If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect to any article subject to this chapter is false or misleading in any particular, he may direct that such use be withheld unless the marking, labeling, or container is modified in such manner as he may prescribe so that it will not be false or misleading. If the person using or proposing to use the marketing, labeling, or container does not accept the determination of the Secretary, such person may request a hearing, but the use of the marking, labeling, or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person adversely affected thereby appeals to the United States Court of Appeals for the circuit in which such person has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

(Pub. L. 85–172, § 8, Aug. 28, 1957, 71 Stat. 444; Pub. L. 90–492, § 8, Aug. 18, 1968, 82 Stat. 799; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in par. (b), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

AMENDMENTS

1968—Par. (a). Pub. L. 90–492 substituted provisions requiring shipping containers and immediate containers, as the Secretary may order, to bear the information required under section 453(h) of this title, and provisions, whenever the Secretary determines such action to be practicable and necessary, requiring nonconsumer packaged carcasses at the time they leave the official establishment to bear the information required under the aforementioned section, for provisions requiring shipping containers to bear the official mark and the approved plant number of the official establishment in which the contents were processed, provisions requiring immediate containers to bear the official inspection mark, the name of the product, a statement of ingredients, the net weight or other appropriate measure of the contents, the name and address of the processor, and the approved plant number of the official establishment in which the contents were processed, and provisions authorizing the Secretary to make reasonable variations and grant exemptions from the foregoing labeling requirements.

Par. (b). Pub. L. 90–492 added par. (b). Provisions of former par. (b) were redesignated as pars. (c) and (d).

Par. (c). Pub. L. 90–492 redesignated part of provisions of former par. (b) as (c) and made changes in phraseology.

Par. (d). Pub. L. 90–492 redesignated part of provisions of former par. (b) as (d) and extended the authority of the Secretary to withhold from use products which have false or misleading markings or containers.

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in par. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 453, 454, 467, 467c of this title.

## § 458. Prohibited acts

(a) No person shall—

(1) slaughter any poultry or process any poultry products which are capable of use as human food at any establishment processing any such articles for commerce, except in compliance with the requirements of this chapter;

(2) sell, transport, offer for sale or transportation, or receive for transportation, in commerce, (A) any poultry products which are capable of use as human food and are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation; or (B) any poultry products required to be inspected under this chapter unless they have been so inspected and passed;

(3) do, with respect to any poultry products which are capable of use as human food, any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such products to be adulterated or misbranded;

(4) sell, transport, offer for sale or transportation, or receive for transportation, in commerce or from an official establishment, any slaughtered poultry from which the blood, feathers, feet, head, or viscera have not been removed in accordance with regulations promulgated by the Secretary, except as may be authorized by regulations of the Secretary;

(5) use to his own advantage, or reveal other than to the authorized representatives of the United States Government or any State or other government in their official capacity, or as ordered by a court in any judicial proceedings, any information acquired under the authority of this chapter concerning any matter which is entitled to protection as a trade secret.

(b) No brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, or any form of official certificate or simulation thereof, except as authorized by the Secretary.

(c) No person shall—

(1) forge any official device, mark, or certificate;

(2) without authorization from the Secretary use any official device, mark, or certificate, or simulation thereof, or alter, detach, deface, or destroy any official device, mark, or certificate;

(3) contrary to the regulations prescribed by the Secretary, fail to use, or to detach, deface, or destroy any official device, mark, or certificate;

(4) knowingly possess, without promptly notifying the Secretary or his representative, any official device or any counterfeit, simulated, forged, or improperly altered official certificate or any device or label or any carcass of any poultry, or part or product thereof, bearing any counterfeit, simulated, forged, or improperly altered official mark;

(5) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary; or

(6) knowingly represent that any article has been inspected and passed, or exempted, under this chapter when, in fact, it has respectively, not been so inspected and passed, or exempted.

(Pub. L. 85–172, § 9, Aug. 28, 1957, 71 Stat. 445; Pub. L. 90–492, § 9, Aug. 18, 1968, 82 Stat. 800.)

AMENDMENTS

1968—Pub. L. 90–492 made revisions in form and phraseology, added to the enumerated prohibited acts slaughtering poultry or processing any poultry products capable of use as human food, except in compliance with the requirements of this chapter, selling and transporting adulterated or misbranded poultry products or uninspected poultry products, adulterating or misbranding poultry products while they are being transported in commerce or held for sale after such transportation, treating carcasses not in accordance with regulations promulgated by the Secretary, possessing, without notifying the Secretary, any official device or any counterfeit, simulated, etc., official certificate, or any device or label bearing any counterfeit, simulated, etc., official mark, and making false representations and statements, and clarified application to brand manufacturers and printers of existing provisions prohibiting the counterfeiting of official marks, labels, or certificates.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, except that amendment of pars. (a)(2)(A) and (a)(3) effective upon the expiration of sixty days after Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

### § 459. Compliance by all establishments

No establishment processing poultry or poultry products for commerce otherwise subject to this chapter shall process any poultry or poultry product except in compliance with the requirements of this chapter.

(Pub. L. 85–172, § 10, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 10, Aug. 18, 1968, 82 Stat. 801.)

AMENDMENTS

1968—Pub. L. 90–492 substituted "otherwise subject to this chapter" for "in or for marketing in a designated major consuming area".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

### § 460. Miscellaneous activities subject to regulation

#### (a) Prohibition of inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles

Inspection shall not be provided under this chapter at any establishment for the slaughter of poultry or the processing of any carcasses or parts or products of poultry, which are not intended for use as human food, but such articles shall, prior to their offer for sale or transportation in commerce, unless naturally inedible by humans, be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food. No person shall buy, sell, transport, or offer for sale or transportation, or receive for transportation, in commerce, or import, any poultry carcasses or parts or products thereof which are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary or are naturally inedible by humans.

#### (b) Recordkeeping requirements; persons liable; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples

The following classes of persons shall, for such period of time as the Secretary may by regulations prescribe, not to exceed two years unless otherwise directed by the Secretary for good cause shown, keep such records as are properly necessary for the effective enforcement of this chapter in order to insure against adulterated or misbranded poultry products for the American consumer; and all persons subject to such requirements shall, at all reasonable times, upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory upon payment of the fair market value therefor—

(1) Any person that engages in the business of slaughtering any poultry or processing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as poultry products brokers, wholesalers or otherwise), or transporting, in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any poultry;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.

**(c) Registration of business, name of person, and trade names**

No person shall engage in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer, or engage in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any poultry, whether intended for human food or other purposes, or engage in business as a public warehouseman storing any such articles in or for commerce, or engage in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, unless when required by regulations of the Secretary, he has registered with the Secretary his name, and the address of each place of business at which, and all trade names under which, he conducts such business.

**(d) Regulation of transactions, transportation, or importation of dead, dying, disabled or diseased poultry or carcasses to prevent use as human food**

No person engaged in the business of buying, selling, or transporting in commerce, or importing, dead, dying, disabled, or diseased poultry, or any parts of the carcasses of any poultry that died otherwise than by slaughter, shall buy, sell, transport, offer for sale or transportation, or receive for transportation, in commerce, or import, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, unless such transaction, transportation or importation is made in accordance with such regulations as the Secretary may prescribe to assure that such poultry, or the unwholesome parts or products thereof, will be prevented from being used for human food.

**(e) Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority**

The authority conferred on the Secretary by paragraph (b), (c), or (d) of this section with respect to persons engaged in the specified kinds of business in or for commerce may be exercised with respect to persons engaged, in any State or organized territory, in such kinds of business but not in or for commerce, whenever the Secretary determines, after consultation with an appropriate advisory committee provided for in section 454 of this title, that the State or territory does not have at least equal authority under its laws or such authority is not exercised in a manner to effectuate the purposes of this chapter, including the State or territory providing for the Secretary or his representative being afforded access to such places of business and the facilities, inventories, and records thereof, and the taking of reasonable samples, where he determines necessary in carrying out his responsibilities under this chapter; and in such case the provisions of paragraph (b), (c), or (d) of this section, respectively, shall apply to such persons to the same extent and in the same manner as if they were engaged in such business in or for commerce and the transactions involved were in commerce.

(Pub. L. 85–172, § 11, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 11, Aug. 18, 1968, 82 Stat. 801.)

AMENDMENTS

1968—Pub. L. 90–492 designated existing provisions as par. (b), added pars. (a), and (c) to (e), and in par. (b), as so designated, extended the types of persons required to maintain records necessary for the enforcement of this chapter, required such persons to give representatives of the Secretary access to their places of business, and opportunity to examine records, facilities, and inventories and to copy records and take inventory samples upon payment.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, except that par. (d) effective upon the expiration of sixty days after Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461, 467e of this title.

## § 461. Offenses and punishment

**(a) Violations; liability of agents, employees, and employers**

Any person who violates the provisions of section 458, 459, 460, 463, or 466 of this title shall be fined not more than $1,000 or imprisoned not more than one year, or both; but if such violation involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except as defined in section 453(g)(8) of this title), such person shall be fined not more than $10,000 or imprisoned not more than three years, or both. When construing or enforcing the provisions of said sections the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association within the scope of his employment or office shall in every case be deemed the act, omission, or failure of such individual, partnership, corporation, or association, as well as of such person.

**(b) Liability of carrier**

No carrier shall be subject to the penalties of this chapter, other than the penalties for violation of section 460 of this title, by reason of his receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of poultry or poultry products, owned by another person unless the carrier has knowledge, or is in possession of facts which would cause a reasonable person to believe that such poultry or poultry products were not inspected or marked in accordance with the provisions of this chapter or were otherwise not eligible for transportation under this chapter or unless the carrier refuses to furnish on request of a representative of the Secretary the name and address of the person from whom he received such poultry or poultry products, and copies of all documents, if any there be, pertaining to the delivery of the poultry or poultry products to such carrier.

**(c) Assaulting, resisting, or impeding certain persons; murder; punishments**

Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account of the performance of his official duties under this chapter shall be fined not more than $5,000 or imprisoned not more than three years, or both. Whoever, in the commission of any such acts, uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than ten years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this chapter shall be punished as provided under sections 1111 and 1114 of title 18.

(Pub. L. 85–172, § 12, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 12, Aug. 18, 1968, 82 Stat. 802.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492, § 12(a), inserted reference to violations of section 463 of this title, and substituted provisions that violators of the enumerated sections shall be fined not more than $1,000 or imprisoned not more than one year, or both, but that in cases involving intent to defraud, or any distribution or attempt to distribute adulterated articles, except as defined in section 453(g) of this title, the violators shall be fined not more than $10,000 or imprisoned not more than three years, or both, for provisions that violators shall be guilty of a misdemeanor and subject to imprisonment for not more than six months or a fine of not more than $3,000, or both, with increased fines and imprisonment for any subsequent violations.

Par. (b). Pub. L. 90–492, § 12(b), substituted ''of poultry'' for ''of slaughtered poultry'', ''such poultry'' for ''such slaughtered poultry'', and ''otherwise not eligible'' for ''not otherwise eligible'', and inserted provision that no carrier shall be subject to punishment unless the carrier refuses to furnish the name and address of the person from whom he received such poultry or poultry products, and copies of any documents pertaining to the delivery of the poultry or poultry products to such carrier.

Par. (c). Pub. L. 90–492, § 12(c), added par. (c).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

## § 462. Reporting of violations; notice; opportunity to present views

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given reasonable notice of the alleged violation and opportunity to present his views orally or in writing with regard to such contemplated proceeding. Nothing in this chapter shall be construed as requiring the Secretary to report for criminal prosecution violations of this chapter whenever he believes that the public interest will be adequately served and compliance with the chapter obtained by a suitable written notice or warning.

(Pub. L. 85–172, § 13, Aug. 28, 1957, 71 Stat. 447.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

## § 463. Rules and regulations

**(a) Storage and handling of poultry products; violation of regulations**

The Secretary may by regulations prescribe conditions under which poultry products capable of use as human food, shall be stored or otherwise handled by any person engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited.

**(b) Other necessary rules and regulations**

The Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of this chapter.

**(c) Oral presentation of views**

In applying the provisions of section 553(c) of title 5 to proposed rule making under this chapter, an opportunity for the oral presentation of views shall be accorded all interested persons.

(Pub. L. 85–172, § 14, Aug. 28, 1957, 71 Stat. 447; Pub. L. 90–492, § 13, Aug. 18, 1968, 82 Stat. 803.)

AMENDMENTS

1968—Pub. L. 90–492 designated existing provisions as par. (b), added pars. (a) and (c), and in par. (b), as so designated, substituted ''such other rules'' for ''such rules''.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

## § 464. Exemptions

**(a) Persons exempted**

The Secretary shall, by regulation and under such conditions as to sanitary standards, practices, and procedures as he may prescribe, exempt from specific provisions of this chapter—

(1) retail dealers with respect to poultry products sold directly to consumers in individual retail stores, if the only processing operation performed by such retail dealers is the cutting up of poultry products on the premises where such sales to consumers are made;

(2) for such period of time as the Secretary determines that it would be impracticable to provide inspection and the exemption will aid in the effective administration of this chapter, any person engaged in the processing of poultry or poultry products for commerce and the poultry or poultry products processed by such person: *Provided, however*, That no such exemption shall continue in effect on and after January 1, 1970; and

(3) persons slaughtering, processing, or otherwise handling poultry or poultry products which have been or are to be processed as required by recognized religious dietary laws, to the extent that the Secretary determines necessary to avoid conflict with such require-

ments while still effectuating the purposes of this chapter.

**(b) Territorial exemption**

The Secretary may, under such sanitary conditions as he may by regulations prescribe, exempt from the inspection requirements of this chapter the slaughter of poultry, and the processing of poultry products, by any person in any Territory not organized with a legislative body, solely for distribution within such Territory, when the Secretary determines that it is impracticable to provide such inspection within the limits of funds appropriated for administration of this chapter and that such exemption will aid in the effective administration of this chapter.

**(c) Personal slaughtering; custom slaughtering; name and address of the poultry producer or processor in lieu of other labeling requirements; small enterprises; slaughterers or processors of specified number of turkeys; poultry producers raising poultry on own farms**

(1) The Secretary shall, by regulation and under such conditions, including sanitary standards, practices, and procedures, as he may prescribe, exempt from specific provisions of this chapter—

(A) the slaughtering by any person of poultry of his own raising, and the processing by him and transportation in commerce of the poultry products exclusively for use by him and members of his household and his nonpaying guests and employees;

(B) the custom slaughter by any person of poultry delivered by the owner thereof for such slaughter, and the processing by such slaughterer and transportation in commerce of the poultry products exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided*, That such custom slaughterer does not engage in the business of buying or selling any poultry products capable of use as human food;

(C) the slaughtering and processing of poultry products in any State or Territory or the District of Columbia by any poultry producer on his own premises with respect to sound and healthy poultry raised on his premises and the distribution by any person solely within such jurisdiction of the poultry products derived from such operations, if, in lieu of other labeling requirements, such poultry products are identified with the name and address of such poultry producer, and if they are not otherwise misbranded, and are sound, clean, and fit for human food when so distributed; and

(D) the slaughtering of sound and healthy poultry or the processing of poultry products of such poultry in any State or territory or the District of Columbia by any poultry producer or other person for distribution by him solely within such jurisdiction directly to household consumers, restaurants, hotels, and boarding houses, for use in their own dining rooms, or in the preparation of meals for sales direct to consumers, if, in lieu of other labeling requirements, such poultry products are identified with the name and address of the processor, and if they are not otherwise misbranded and are sound, clean, and fit for human food when distributed by such processor.

The exemptions provided for in clauses (C) and (D) above shall not apply if the poultry producer or other person engages in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in such clauses.

(2) In addition to the specific exemptions provided herein, the Secretary shall, when he determines that the protection of consumers from adulterated or misbranded poultry products will not be impaired by such action, provide by regulation, consistent with subparagraph (3), for the exemption of the operation and products of small enterprises (including poultry producers), not exempted under subparagraph (1), which are engaged in any State or Territory or the District of Columbia in slaughtering and/or cutting up poultry for distribution as carcasses or parts thereof solely for distribution within such jurisdiction, from such provisions of this chapter as he deems appropriate, while still protecting the public from adulterated or misbranded products, under such conditions, including sanitary requirements, as he shall prescribe to effectuate the purposes of this chapter.

(3) No exemption under subparagraph (1)(C) or (D) or subparagraph (2) shall apply to any poultry producer or other person who, in the current calendar year—

(A) slaughters or processes the products of more than 20,000 poultry; or

(B) slaughters or processes the products of poultry at a facility used for slaughtering or processing of the products of poultry by any other poultry producer or person.

Notwithstanding clause (B), the Secretary may grant such exemption to any poultry producer or other person if the Secretary determines, upon application of such poultry producer or other person, that granting such exemption will not impair effectuating the purposes of this chapter.

(4) The provisions of this chapter shall not apply to poultry producers with respect to poultry of their own raising on their own farms if (i) such producers slaughter not more than 1,000 poultry during the calendar year for which this exemption is being determined; (ii) such poultry producers do not engage in buying or selling poultry products other than those produced from poultry raised on their own farms; and (iii) none of such poultry moves in commerce (as defined in section 453(a) of this title).

**(d) Pizzas containing poultry products**

(1) Under such terms and conditions as the Secretary shall prescribe through rules and regulations issued under this section that may be necessary to ensure food safety and protect public health such as special handling procedures, the Secretary shall exempt pizzas containing a poultry product from the inspection requirements of this chapter if—

(A) the poultry product components of the pizzas have been prepared, inspected, and passed in a cured or cooked form as ready-to-

eat in compliance with the requirements of this chapter; and

(B) the pizzas are to be served in public or private nonprofit institutions.

(2) The Secretary may withdraw or modify any exemption under this subsection whenever the Secretary determines such action is necessary to ensure food safety and to protect public health. The Secretary may reinstate or further modify any exemption withdrawn or modified under this subsection.

**(e) Applicability of adulteration and misbranding provisions to articles exempted from inspection**

The adulteration and misbranding provisions of this chapter, other than the requirement of the inspection legend, shall apply to articles which are exempted from inspection under this section, except as otherwise specified under paragraphs (a) and (d).

**(f) Suspension or termination of exemption**

The Secretary may by order suspend or terminate any exemption under this section with respect to any person whenever he finds that such action will aid in effectuating the purposes of this chapter.

(Pub. L. 85–172, § 15, Aug. 28, 1957, 71 Stat. 447; Pub. L. 90–492, § 14, Aug. 18, 1968, 82 Stat. 803; Pub. L. 97–206, June 30, 1982, 96 Stat. 136; Pub. L. 102–237, title X, § 1016(b), Dec. 13, 1991, 105 Stat. 1903.)

AMENDMENTS

1991—Subsecs. (d) to (f). Pub. L. 102–237 added subsec. (d), redesignated former subsec. (d) as (e) and substituted ''(d)'' for ''(c)'', and redesignated former subsec. (e) as (f).

1982—Par. (c)(3). Pub. L. 97–206, § 1, substituted provisions that no exemption would be given to persons who during the current calendar year either slaughter or process the products of more than 20,000 poultry, or slaughter or process such poultry at a facility of another poultry producer or person, but that, in the latter case, the Secretary may grant the exemption upon application of such poultry producer or person if granting such exemption would not impair the purposes of this chapter, for provisions that an exemption would not be granted to those who slaughter or process the products of more than 5,000 turkeys or an equivalent number of poultry of all species in the current calendar year (four birds of other species being deemed equivalent of one turkey).

Par. (c)(4)(i). Pub. L. 97–206, § 2, substituted ''1,000 poultry during the calendar year for which this exemption is being determined'' for ''250 turkeys, or not more than an equivalent number of birds of all species during the calendar year for which this exemption is being determined (four birds of other species being deemed the equivalent of one turkey)''.

1968—Par. (a). Pub. L. 90–492, § 14(a), (b), redesignated subpars. (2) to (4) as (1) to (3), respectively, and in subpar. (2), as so redesignated, substituted ''January 1, 1970'' for ''July 1, 1960''. Former subpar. (1), which exempted poultry producers with respect to poultry of their own raising on their own farms which they sold directly to household consumers, hotels, etc., for use in their own dining rooms or in the preparation of meals for sales direct to consumers only, provided that such producers did not engage in buying or selling poultry products other than those produced from poultry raised on their own farms, was struck out.

Pars. (b) to (e). Pub. L. 90–492, § 14(c), added pars. (b) to (d) and redesignated former par. (b) as (e).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective upon the expiration of sixty days after Aug. 18, 1968, see section 20(b) of Pub. L. 90–492, set out as a note under section 451 of this title.

REGULATIONS

Section 1016(c) of Pub. L. 102–237 provided that: ''No later than August 1, 1992, the Secretary of Agriculture shall issue final rules, through prior notice and comment rulemaking procedures, to implement the exemption authorized by section 23(c) of the Federal Meat Inspection Act [21 U.S.C. 623(c)] (as added by subsection (a)) and the exemption authorized by section 15(d) of the Poultry Products Inspection Act [21 U.S.C. 464(d)] (as added by subsection (b)). Prior to the issuance of the final rules, the Secretary shall hold at least one public hearing examining the public health and food safety issues raised by the granting of each of the exemptions.''

STUDIES CONCERNING GRANT OF FUTURE EXEMPTIONS FOR POULTRY AND MEAT FOOD PRODUCTS

Section 1016(d) of Pub. L. 102–237 directed Secretary of Agriculture in consultation with National Academy of Sciences to conduct a study on meat food and poultry products inspection exemptions under Federal Meat Inspection Act and Poultry Products Inspection Act and a study on an exemption from requirements of such Acts for certain wholesale meat outlets selling to hotels and other similar institutional users not later than 24 months after Dec. 13, 1991, and on completion of each study to provide the results to Committee on Agriculture of House of Representatives and Committee on Agriculture, Nutrition, and Forestry of Senate.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

## § 465. Limitations upon entry of poultry products and other materials into official establishments

The Secretary may limit the entry of poultry products and other materials into any official establishment, under such conditions as he may prescribe to assure that allowing the entry of such articles into such inspected establishments will be consistent with the purposes of this chapter.

(Pub. L. 85–172, § 16, Aug. 28, 1957, 71 Stat. 448; Pub. L. 90–492, § 15, Aug. 18, 1968, 82 Stat. 805.)

AMENDMENTS

1968—Pub. L. 90–492 substituted provisions authorizing the Secretary to limit the entry of poultry products and other materials into any official establishment for provisions that any person distributing unwholesome or adulterated exempted poultry or poultry products intended for human consumption shall be guilty of a misdemeanor and subject to penalties upon conviction thereof.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

## § 466. Imports

**(a) Compliance with standards and regulations; status after importation**

No slaughtered poultry, or parts or products thereof, of any kind shall be imported into the

United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, adulterated, or unfit for human food and unless they also comply with the rules and regulations made by the Secretary of Agriculture to assure that imported poultry or poultry products comply with the standards provided for in this chapter. All imported, slaughtered poultry, or parts or products thereof, shall after entry into the United States in compliance with such rules and regulations be deemed and treated as domestic slaughtered poultry, or parts or products thereof, within the meaning and subject to the provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and Acts amendatory of, supplemental to, or in substitution for such chapter and Act.

**(b) Rules and regulations; destruction and exportation of refused imports**

The Secretary of Agriculture is authorized to make rules and regulations to carry out the purposes of this section and in such rules and regulations the Secretary of Agriculture may prescribe the terms and conditions for the destruction of all slaughtered poultry, or parts or products thereof, offered for entry and refused admission into the United States unless such slaughtered poultry, or parts or products thereof, be exported by the consignee within the time fixed therefor in such rules and regulations.

**(c) Storage, cartage and labor charges for imports refused admission**

All charges for storage, cartage, and labor with respect to any product which is refused admission pursuant to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any other products imported thereafter by or for such owner or consignee.

**(d) Domestic standards and processing facilities applicable; enforcement**

(1) Notwithstanding any other provision of law, all poultry, or parts or products of poultry, capable of use as human food offered for importation into the United States shall—

(A) be subject to inspection, sanitary, quality, species verification, and residue standards that achieve a level of sanitary protection equivalent to that achieved under United States standards; and

(B) have been processed in facilities and under conditions that achieve a level of sanitary protection equivalent to that achieved under United States standards.

(2)(A) The Secretary may treat as equivalent to a United States standard a standard of an exporting country described in paragraph (1) if the exporting country provides the Secretary with scientific evidence or other information, in accordance with risk assessment methodologies determined appropriate by the Secretary, to demonstrate that the standard of the exporting country achieves the level of sanitary protection achieved under the United States standard. For the purposes of this subsection, the term ''sanitary protection'' means protection to safeguard public health.

(B) The Secretary may—

(i) determine, on a scientific basis, that the standard of the exporting country does not achieve the level of protection that the Secretary considers appropriate; and

(ii) provide the basis for the determination in writing to the exporting country on request.

(3) Any such imported poultry article that does not meet such standards shall not be permitted entry into the United States.

(4) The Secretary shall enforce this subsection through—

(A) random inspections for such species verification and for residues; and

(B) random sampling and testing of internal organs and fat of carcasses for residues at the point of slaughter by the exporting country, in accordance with methods approved by the Secretary.

(Pub. L. 85–172, § 17, Aug. 28, 1957, 71 Stat. 448; Pub. L. 99–198, title XVII, § 1701(a), Dec. 23, 1985, 99 Stat. 1633; Pub. L. 103–182, title III, § 361(e), Dec. 8, 1993, 107 Stat. 2123; Pub. L. 103–465, title IV, § 431(k), Dec. 8, 1994, 108 Stat. 4969.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in par. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

AMENDMENTS

1994—Subsec. (d)(1). Pub. L. 103–465, § 431(k)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''Notwithstanding any other provision of law, except as provided in paragraph (2), all poultry, or parts or products thereof, capable of use as human food offered for importation into the United States shall—

''(A) be subject to the same inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States; and

''(B) have been processed in facilities and under conditions that are the same as those under which similar products are processed in the United States.''

Subsec. (d)(2)(A). Pub. L. 103–465, § 431(k)(2)(A), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''Notwithstanding any other provision of law, all poultry, or parts or products of poultry, capable of use as human food offered for importation into the United States from Canada and Mexico shall—

''(i) comply with paragraph (1); or

''(ii)(I) be subject to inspection, sanitary, quality, species verification, and residue standards that are equivalent to United States standards; and

''(II) have been processed in facilities and under conditions that meet standards that are equivalent to United States standards.''

Subsec. (d)(2)(B), (C). Pub. L. 103–465, § 431(k)(2)(B), (C), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: ''The Secretary may treat as equivalent to a United States standard a standard of Canada or Mexico described in subparagraph (A)(ii) if the exporting country provides the Secretary with scientific evidence or other information, in accordance with risk assessment methodologies agreed to by the Secretary and the exporting country, to demonstrate that the standard of the exporting country achieves the level of protection that the Secretary considers appropriate.''

1993—Subsec. (d). Pub. L. 103–182, in par. (1), inserted ''except as provided in paragraph (2),'' before ''all poul-

try'' in introductory provisions, added par. (2), and redesignated former pars. (2) and (3) as (3) and (4), respectively.

1985—Par. (d). Pub. L. 99–198 added par. (d).

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective, except as otherwise provided, on the date of entry into force of the World Trade Organization Agreement with respect to the United States [Jan. 1, 1995], see section 451 of Pub. L. 103–465, set out as an Effective Date note under section 3601 of Title 19, Customs Duties.

EFFECTIVE DATE OF 1985 AMENDMENT

Section 1701(b) of Pub. L. 99–198 proved that: ''The amendment made by this section [amending this section] shall become effective 6 months after the date of enactment of this Act [Dec. 23, 1985].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

### § 467. Inspection services

#### (a) Refusal or withdrawal; hearing; business unfitness based upon certain convictions; persons responsibly connected with the business

The Secretary may (for such period, or indefinitely, as he deems necessary to effectuate the purposes of this chapter) refuse to provide, or withdraw, inspection service under this chapter with respect to any establishment if he determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection upon this chapter because the applicant or recipient or anyone responsibly connected with the applicant or recipient, has been convicted, in any Federal or State court, within the previous ten years of (1) any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food or fraud in connection with transactions in food; or (2) any felony, involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health. For the purpose of this paragraph a person shall be deemed to be responsibly connected with the business if he was a partner, officer, director, holder, or owner of 10 per centum or more of its voting stock or employee in a managerial or executive capacity.

#### (b) Hearing to determine validity of withdrawal or refusal of inspection services; continuation of withdrawal or refusal

Upon the withdrawal of inspection service from any official establishment for failure to destroy condemned poultry products as required under section 455 of this title, or other failure of an official establishment to comply with the requirements as to premises, facilities, or equipment, or the operation thereof, as provided in section 456 of this title, or the refusal of inspection service to any applicant therefor because of failure to comply with any requirements under section 456 of this title, the applicant for, or recipient of, the service shall, upon request, be afforded opportunity for a hearing with respect to the merits or validity of such action; but such withdrawal or refusal shall continue in effect unless otherwise ordered by the Secretary.

#### (c) Finality and conclusiveness of determination; judicial review; record

The determination and order of the Secretary when made after opportunity for hearing, with respect to withdrawal or refusal of inspection service under this chapter shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within thirty days after the effective date of such order in the United States Court of Appeals as provided in section 457 of this title. Judicial review of any such order shall be upon the record upon which the determination and order are based. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

(Pub. L. 85–172, § 18, Aug. 28, 1957, 71 Stat. 448; Pub. L. 90–492, § 16, Aug. 18, 1968, 82 Stat. 805.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492 substituted provisions authorizing the Secretary to refuse or withdraw inspection services subsequent to a hearing determining that the applicant or recipient is unfit to engage in any business requiring inspection under this chapter based upon the specified considerations, for provisions granting the Secretary exclusive jurisdiction within the scope of this chapter and exempting poultry and poultry products from the provisions of the Federal Food, Drug, and Cosmetic Act, as amended, to the extent of the application or the extension thereof of the provisions of this chapter.

Par. (b). Pub. L. 90–492 substituted provisions granting a hearing, upon request by the applicant or recipient, to determine the merits and validity of the withdrawal or refusal of inspection services and continuing such withdrawal or refusal in effect, unless otherwise ordered by the Secretary, for provisions authorizing the Secretary to cooperate with other branches of government and with State agencies and to conduct examinations, investigations, and inspections through any officer or employee of a State commissioned by the Secretary for such purpose.

Par. (c). Pub. L. 90–492 added par. (c).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as a note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467c of this title.

### § 467a. Administrative detention; duration; pending judicial proceedings; notification of government authorities; release; removal of official marks

Whenever any poultry product, or any product exempted from the definition of a poultry product, or any dead, dying, disabled, or diseased poultry is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to this chapter, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provi-

sions of this chapter or of any other Federal law or the laws of any State or Territory, or the District of Columbia, or that it has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under section 467b of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or poultry, and shall not be moved by any person, from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or poultry before it is released unless it appears to the satisfaction of the Secretary that the article or poultry is eligible to retain such marks.

(Pub. L. 85–172, § 19, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 805.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467f of this title.

### § 467b. Seizure and condemnation

**(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bonds; court costs and fees, storage, and other expenses against claimants; jury trial; United States as plaintiff**

(1) Any poultry product, or any dead, dying, disabled, or diseased poultry, that is being transported in commerce or otherwise subject to this chapter, or is held for sale in the United States after such transportation, and that (A) is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of this chapter, or (B) is capable of use as human food and is adulterated or misbranded, or (C) in any other way is in violation of this chapter, shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court as provided in section 467c of this title within the jurisdiction of which the article or poultry is found.

(2) If the article or poultry is condemned it shall, after entry of the decree, (A) be distributed in accordance with paragraph (5), or (B) be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the article or poultry shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold: *Provided*, That upon the execution and delivery of a good and sufficient bond conditioned that the article or poultry shall not be sold or otherwise disposed of contrary to the provisions of this chapter, or the laws of the jurisdiction in which disposal is made, the court may direct that such article or poultry be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws.

(3) When a decree of condemnation is entered against the article or poultry and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the article or poultry.

(4) The proceedings in such libel cases shall conform, as nearly as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(5)(A) An article that is condemned under paragraph (1) may as the court may direct, after entry of the decree, be distributed without charge to nonprofit, private entities or to Federal, State, or local government entities engaged in the distribution of food without charge to individuals, if such article—

(i) is capable of use as a human food;

(ii) has been inspected under this chapter and found to be wholesome and not to be adulterated within the meaning of paragraphs (1) through (7) of section 453(g) of this title and a determination is made at the time of the entry of the decree that such article is wholesome and not so adulterated; and

(iii) is plainly marked ''Not for Sale'' on such article or its container.

(B) The United States may not be held legally responsible for any article that is distributed under subparagraph (A) to a nonprofit, private entity or to a Federal, State, or local government entity, if such article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of paragraphs (1) through (7) of section 453(g) of this title and a determination was made at the time of the entry of the decree that such article was wholesome and not so adulterated; and

(ii) was plainly marked ''Not for Sale'' on such article or its container.

(C) The person from whom such article was seized and condemned may not be held legally responsible for such article, if such article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of paragraphs (1) through (7) of section 453(g) of this title and a determination was made at the time of entry of the decree that such article was wholesome and not so adulterated; and

(ii) was plainly marked ''Not for Sale'' on such article or its container.

**(b) Condemnation or seizure under other provisions unaffected**

The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

(Pub. L. 85–172, § 20, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 806; amended Pub. L. 101–205, § 2, Dec. 7, 1989, 103 Stat. 1830.)

AMENDMENTS

1989—Subsec. (a). Pub. L. 101–205 designated first sentence as par. (1) and redesignated cls. (1) to (3) as cls. (A) to (C), respectively, designated second sentence as

par. (2) and inserted ''(A) be distributed in accordance with paragraph (5), or (B)'' after ''entry of the decree,'', designated third and fourth sentences as pars. (3) and (4), respectively, and added par. (5).

FEDERAL RULES OF CIVIL PROCEDURE

Admiralty and maritime rules of practice (which included libel procedures) were superseded, and civil and admiralty procedures in United States district courts were unified, effective July 1, 1966, see rule 1 and Supplemental Rules for Certain Admiralty and Maritime Claims, Title 28, Appendix, Judiciary and Judicial Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467a of this title.

### § 467c. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations; United States as plaintiff; subpenas

The United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other kinds of cases arising under this chapter, except as provided in section 457(d) or 467 of this title. All proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States. Subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

(Pub. L. 85–172, § 21, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 806.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467b, 467d of this title.

### § 467d. Administration and enforcement; applicability of penalty provisions; conduct of inquiries; power and jurisdiction of courts

For the efficient administration and enforcement of this chapter, the provision (including penalties) of sections 46, 48, 49 and 50 of title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49[1] of title 15), and the provisions of section 409(*l*)[1] of title 47, are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of title 15 on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 467c of this title.

(Pub. L. 85–172, § 22, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807.)

[1] See References in Text note below.

REFERENCES IN TEXT

The last paragraph of section 49 of title 15, and the provisions of section 409(*l*) of title 47, referred to in text, which related to immunity of witnesses, were repealed by sections 211 and 242, respectively, of Pub. L. 91–452, Oct. 15, 1970, title II, 84 Stat. 929, 930. For provisions relating to immunity of witnesses, see section 6001 et seq. of Title 18, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

### § 467e. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters

Requirements within the scope of this chapter with respect to premises, facilities and operations of any official establishment which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of paragraph (b) of section 460 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements (or storage or handling requirements found by the Secretary to unduly interfere with the free flow of poultry products in commerce) in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any official establishment in accordance with the requirements under this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter exercise concurrent jurisdiction with the Secretary over articles required to be inspected under this chapter for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

(Pub. L. 85–172, § 23, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807.)

### § 467f. Federal Food, Drug, and Cosmetic Act applications

#### (a) Exemptions; authorities under food, drug, and cosmetic provisions unaffected

Poultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et. seq.] to the extent of the application or extension thereto of the provisions of this chapter, except that the provisions of this chapter shall not derogate

from any authority conferred by the Federal Food, Drug, and Cosmetic Act prior to August 18, 1968.

**(b) Enforcement proceedings; detainer authority of representatives of Secretary of Health and Human Services**

The detainer authority conferred by section 467a of this title shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] with respect to any poultry carcass, or part or product thereof, that is outside any official establishment, and for such purposes the first reference to the Secretary in section 467a of this title shall be deemed to refer to the Secretary of Health, Education, and Welfare.

(Pub. L. 85–172, § 24, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807; amended Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in par. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

### § 468. Cost of inspection; overtime

The cost of inspection rendered under the requirements of this chapter, shall be borne by the United States, except that the cost of overtime and holiday work performed in establishments subject to the provisions of this chapter at such rates as the Secretary may determine shall be borne by such establishments. Sums received by the Secretary in reimbursement for sums paid out by him for such premium pay work shall be available without fiscal year limitation to carry out the purposes of this section.

(Pub. L. 85–172, § 25, formerly § 19, Aug. 28, 1957, 71 Stat. 448, renumbered Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 805.)

### § 469. Authorization of appropriations

There is authorized to be appropriated such sums as are necessary to carry out the provisions of this chapter.

(Pub. L. 85–172, § 26, formerly § 20, Aug. 28, 1957, 71 Stat. 449, renumbered Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 805.)

### § 470. Reports to Congress

The Secretary shall annually report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate with respect to the slaughter of poultry subject to this chapter, and the preparation, storage, handling, and distribution of poultry parts, poultry products, and inspection of establishments operated in connection therewith, including the operations under and the effectiveness of this chapter.

(Pub. L. 85–172, § 27, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807; amended Pub. L. 103–437, § 8(1), Nov. 2, 1994, 108 Stat. 4588.)

AMENDMENTS

1994—Pub. L. 103–437 substituted ''Agriculture, Nutrition, and Forestry'' for ''Agriculture and Forestry''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

## CHAPTER 11—MANUFACTURE OF NARCOTIC DRUGS

### §§ 501 to 517. Repealed. Pub. L. 91–513, title III, § 1101(a)(10), Oct. 27, 1970, 84 Stat. 1292

Sections, Pub. L. 86–429, Apr. 22, 1960, 74 Stat. 55, provided for licensing and control of the manufacture of all narcotic drugs and was known as the ''Narcotic Manufacturing Act of 1960''. Sections 1 to 3 and 5 to 22 of said Pub. L. 86–429 were classified respectively to sections 501, 501 notes, and 502 to 517 of this title. Section 4 of Pub. L. 86–429 was classified to sections 4702, 4731, and 4731 note of Title 26, Internal Revenue Code. See section 801 et seq. of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91–513, set out as a note under section 951 of this title. For provisions postponing such effective date if the Attorney General postpones the effective date of section 826 of this title, see section 1105(c) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91–513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91–513, set out as a note under sections 171 to 174 of this title.

## CHAPTER 12—MEAT INSPECTION

SUBCHAPTER I—INSPECTION REQUIREMENTS; ADULTERATION AND MISBRANDING

Sec.
601. Definitions.
602. Congressional statement of findings.
603. Inspection of meat and meat food products.
(a) Examination of animals before slaughtering; diseased animals slaughtered separately and carcasses examined.
(b) Humane methods of slaughter.
604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection.
605. Examination of carcasses brought into slaughtering or packing establishments, and of meat food products issued from and returned thereto; conditions for entry.
606. Inspectors of meat food products; marks of inspection; destruction of condemned products; products for export.
607. Labeling, marking, and container requirements.
(a) Labeling receptacles or coverings of meat or meat food products inspected and passed; supervision by inspectors.

Sec.
(b) Information on articles or containers; legible form.
(c) Labeling: type styles and sizes; definitions and standards of identity or composition; standards of fill of container; consistency of Federal and Federal-State standards.
(d) Sales under false or misleading name, other marking or labeling or in containers of misleading form or size; trade names, and other marking, labeling, and containers approved by Secretary.
(e) Use withholding directive respecting false or misleading marking, labeling, or container; modification of false or misleading matter; hearing; withholding use pending proceedings; finality of Secretary's action; judicial review; application of section 194 of title 7.
608. Sanitary inspection and regulation of slaughtering and packing establishments; rejection of adulterated meat or meat food products.
609. Examination of animals and food products thereof, slaughtered and prepared during nighttime.
610. Prohibited acts.
(a) Slaughtering animals or preparation of articles capable of use as human food.
(b) Humane methods of slaughter.
(c) Sales, transportation, and other transactions.
(d) Adulteration or misbranding.
611. Devices, marks, labels, and certificates; simulations.
(a) Devices to be made under authorization of Secretary.
(b) Other misconduct.
612. Inspection of animals for export.
613. Inspectors of animals for export; certificates of condition.
614. Clearance prohibited to vessel carrying animals for export without inspector's certificate.
615. Inspection of carcasses, meat of which is intended for export.
616. Inspectors of carcasses, etc., meat of which is intended for export; certificates of condition.
617. Clearance prohibited to vessel carrying meat for export without inspector's certificate.
618. Delivery of inspectors' certificates, and of copies.
619. Marking, labeling, or other identification of kinds of animals of articles' derivation; separate establishments for preparation and slaughtering activities.
620. Imports.
(a) Adulteration or misbranding prohibition; compliance with inspection, building construction standards, and other provisions; humane methods of slaughter; treatment as domestic articles subject to this chapter and food, drug, and cosmetic provisions; marking and labeling; personal consumption exemption.
(b) Terms and conditions for destruction.
(c) Payment of storage, cartage, and labor charges by owner or consignee; liens.
(d) Prohibition.
(e) Reports to Congressional committees.
(f) Inspection and other standards; applicability, enforcement, etc.; certifications.
(g) Administration of animal drugs or antibiotics; terms and conditions; entry order violations.
(h) Reciprocal meat inspection requirement.
621. Inspectors to make examinations provided for; appointment; duties; regulations.
622. Bribery of or gifts to inspectors or other officers and acceptance of gifts.
623. Exemptions from inspection requirements.
(a) Personal slaughtering and custom slaughtering for personal, household, guest, and employee uses.
(b) Territorial exemption; refusal, withdrawal, or modification.
(c) Pizzas containing meat food products.
(d) Adulteration and misbranding provisions applicable to inspection-free articles.
624. Storage and handling regulations; violations; exemption of establishments subject to non-Federal jurisdiction.

SUBCHAPTER II—MEAT PROCESSORS AND RELATED INDUSTRIES

641. Prohibition of subchapter I inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles.
642. Recordkeeping requirements.
(a) Classes of persons bound; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples.
(b) Period of maintenance.
643. Registration of business, name of person, and trade names.
644. Regulation of transactions, transportation, or importation of 4–D animals to prevent use as human food.
645. Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority.

SUBCHAPTER III—FEDERAL AND STATE COOPERATION

661. Federal and State cooperation.
(a) Congressional statement of policy.
(b) Single State agency; subordinate governmental unit as part of State agency.
(c) State meat inspection requirements.
(d) ''State'' defined.

SUBCHAPTER IV—AUXILIARY PROVISIONS

671. Inspection services; refusal or withdrawal; hearing; business unfitness based upon certain convictions; other provisions for withdrawal of services unaffected; responsible connection with business; finality of Secretary's actions; judicial review; record.
672. Administrative detention; duration; pending judicial proceedings; notification of governmental authorities; release.
673. Seizure and condemnation.
(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bond; court costs and fees, storage, and other expenses against claimants; proceedings in admiralty; jury trial; United States as plaintiff.
(b) Condemnation or seizure under other provisions unaffected.
674. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations of section 607(e) of this title.

Sec.
675. Assaulting, resisting, or impeding certain persons; murder; protection of such persons.
676. Violations.
(a) Misdemeanors; felonies: intent to defraud and distribution of adulterated articles; good faith.
(b) Minor violations; written notice of warning of criminal and civil proceedings.
677. Other Federal laws applicable for administration and enforcement of chapter; location of inquiries; jurisdiction of Federal courts.
678. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters.
679. Application of Federal Food, Drug, and Cosmetic Act.
(a) Authorities under food, drug, and cosmetic provisions unaffected.
(b) Enforcement proceedings; detainer authority of representatives of Secretary of Health and Human Services.
680. Authorization of appropriations.

SUBCHAPTER V—MISCELLANEOUS PROVISIONS

691. Reports to Congressional committees.
692. Inspection extended to reindeer.
693. Inspection of dairy products for export.
694. Authorization of appropriations.
695. Payment of cost of meat-inspection service; exception.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 321, 392 of this title; title 7 sections 138f, 6519.

## SUBCHAPTER I—INSPECTION REQUIREMENTS; ADULTERATION AND MISBRANDING

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 641, 661, 671, 672, 673, 678 of this title.

### § 601. Definitions

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

(a) The term ''Secretary'' means the Secretary of Agriculture of the United States or his delegate.

(b) The term ''firm'' means any partnership, association, or other unincorporated business organization.

(c) The term ''meat broker'' means any person, firm, or corporation engaged in the business of buying or selling carcasses, parts of carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person, firm, or corporation.

(d) The term ''renderer'' means any person, firm, or corporation engaged in the business of rendering carcasses or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines, except rendering conducted under inspection or exemption under this subchapter.

(e) The term ''animal food manufacturer'' means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts of products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines.

(f) The term ''State'' means any State of the United States and the Commonwealth of Puerto Rico.

(g) The term ''Territory'' means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(h) The term ''commerce'' means commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

(i) The term ''United States'' means the States, the District of Columbia, and the Territories of the United States.

(j) The term ''meat food product'' means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(k) The term ''capable of use as human food'' shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.

(*l*) The term ''prepared'' means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(m) The term ''adulterated'' shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw

agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title,

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

(n) The term ''misbranded'' shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(4) if its container is so made, formed, or filled as to be misleading;

(5) if in a package or other container unless it bears a label showing (A) the name and place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 607 of this title unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 607 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) if it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(10) if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall

be established by regulations promulgated by the Secretary; or

(12) if it fails to bear, directly thereon or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(*o*) The term ''label'' means a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

(p) The term ''labeling'' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(q) The term ''Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]'' means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

(r) The terms ''pesticide chemical,'' ''food additive,'' ''color additive,'' and ''raw agricultural commodity'' shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(s) The term ''official mark'' means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this chapter.

(t) The term ''official inspection legend'' means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this chapter.

(u) The term ''official certificate'' means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(v) The term ''official device'' means any device prescribed or authorized by the Secretary for use in applying any official mark.

(Mar. 4, 1907, ch. 2907, title I, § 1, as added Dec. 15, 1967, Pub. L. 90–201, § 2, 81 Stat. 584; amended Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695; Oct. 29, 1992, Pub. L. 102–571, title I, § 107(14), 106 Stat. 4499.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in pars. (q) and (r), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

AMENDMENTS

1992—Subsec. (m)(2)(D). Pub. L. 102–571 substituted ''379e'' for ''376''.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in par. (n)(10) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE

Section 20 of Pub. L. 90–201 provided that: ''This Act [see Short Title note below] shall become effective upon enactment [Dec. 15, 1967] except as provided in paragraphs (a) through (d):

''(a) The provisions of paragraph (b)(1) and (c) of section 10 and the provisions of section 20 of the Federal Meat Inspection Act, as amended by sections 7 and 10 of this Act [sections 610 and 620 of this title], and the provisions of section 18 of this Act repealing paragraph (b) of section 306 of the Tariff Act of 1930 [section 1306(b) of Title 19, Customs Duties], shall become effective upon the expiration of sixty days after enactment [Dec. 15, 1967], hereof.

''(b) The provisions of title I of the Federal Meat Inspection Act, as amended by this Act [this subchapter], shall become effective with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof upon the expiration of sixty days after enactment [Dec. 15, 1967] hereof.

''(c) Section 11 of this Act, amending section 23, of the Federal Meat Inspection Act [section 623 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967].

''(d) Section 204 of the Federal Meat Inspection Act, as added by section 14 of this Act [section 644 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967].''

SHORT TITLE OF 1986 AMENDMENT

Pub. L. 99–641, title IV, § 401, Nov. 10, 1986, 100 Stat. 3567, provided that: ''This title [amending sections 606, 609, 621, 671, and 676 of this title and enacting provisions set out as notes under sections 606, 609, 621, 671, and 676 of this title] may be cited as the 'Processed Products Inspection Improvement Act of 1986'.''

SHORT TITLE OF 1978 AMENDMENT

Pub. L. 95–445, § 1, Oct. 10, 1978, 92 Stat. 1069, provided: ''That this Act [amending sections 603, 610, and 620 of this title and sections 1902 and 1904 of Title 7, Agriculture, repealing sections 1903 and 1905 of Title 7, and enacting provisions set out as notes under this section and section 603 of this title] may be cited as the 'Humane Methods of Slaughter Act of 1978'.''

SHORT TITLE

Section 1 of Pub. L. 90–201 provided in part: ''That this Act [enacting this section and sections 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amending sections 603 to 623 of this title, repealing section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacting provisions set out as notes under this section] may be cited as the 'Wholesome Meat Act'.''

Section 1 of Pub. L. 90–201 provided in part that the provisions of act Mar. 4, 1907, as amended, classified to subchapters I to IV of this chapter, are designated as the ''Federal Meat Inspection Act''.

SEPARABILITY

Section 19 of Pub. L. 90–201 provided that: ''If any provision of this Act or of the amendments made hereby [see Short Title note above] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act and the remaining amendments [see Short Title note above] and of the application of such provision to other persons and circumstances shall not be affected thereby.''

ACT REFERRED TO IN OTHER SECTIONS

The Wholesome Meat Act is referred to in section 1053 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 607, 673, 676 of this title; title 15 sections 2052, 2602.

### § 602. Congressional statement of findings

Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

(Mar. 4, 1907, ch. 2907, title I, § 2, as added Dec. 15, 1967, Pub. L. 90–201, § 2, 81 Stat. 587.)

### § 603. Inspection of meat and meat food products

#### (a) Examination of animals before slaughtering; diseased animals slaughtered separately and carcasses examined

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

#### (b) Humane methods of slaughter

For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which cattle, sheep, swine, goats, horses, mules, and other equines are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter. The Secretary may refuse to provide inspection to a new slaughtering establishment or may cause inspection to be temporarily suspended at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at such establishment by any method not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901–1906) until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with such a method.

(Mar. 4, 1907, ch. 2907, title I, § 3, formerly 1st par., 34 Stat. 1260; renumbered § 3 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3, 12(a), (b), 81 Stat. 584, 588, 592; Oct. 10, 1978, Pub. L. 95–445, § 2, 92 Stat. 1069.)

REFERENCES IN TEXT

Act of August 27, 1958, referred to in subsec. (b), is Pub. L. 85–765, Aug. 27, 1958, 72 Stat. 862, as amended, which is classified generally to chapter 48 (§ 1901 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Tables.

Sections 1903 and 1905 of Title 7, included within reference to Act of August 27, 1958, were repealed by Pub. L. 95–445, § 5(b), Oct. 10, 1978, 92 Stat. 1069, effective as set forth in section 7 of Pub. L. 95–445, set out as an Effective Date of 1978 Amendment note below.

CODIFICATION

Section was formerly classified to section 71 of this title.

AMENDMENTS

1978—Pub. L. 95–445 designated existing provisions as subsec. (a) and added subsec. (b).

1967—Pub. L. 90–201, §§ 3, 12(a), (b), struck out "interstate or foreign" before "commerce" in two places, substituted "Secretary shall" for "Secretary, at his discretion, may", and struck out "of Agriculture" after "Secretary", included horses, mules, and other equines, and horses, mules, or other equines in the list of animals, and substituted "adulterated" for "unsound, unhealthful, unwholesome, or otherwise unfit for human food", respectively.

EFFECTIVE DATE OF 1978 AMENDMENT

Section 7 of Pub. L. 95–445 provided that: "The provisions of this Act [see Short Title of 1978 Amendment note set out under section 601 of this title] shall become effective one year after the date of enactment [Oct. 10, 1978]. However, such provisions shall not apply to a person, firm, or corporation for such additional period of time, not to exceed eighteen months, as may be determined by the Secretary, if the Secretary, upon application, finds that compliance with the provisions of this Act on its effective date would cause undue hardship on such person, firm, or corporation."

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

RELIGIOUS FREEDOM; RITUAL SLAUGHTER

Section 6 of Pub. L. 95–445 provided that: ''Nothing in this Act [see Short Title of 1978 Amendment note set out under section 601 of this title] shall be construed to prohibit, abridge, or in any way hinder the religious freedom of any person or group. Notwithstanding any other provision of this Act, in order to protect freedom of religion, ritual slaughter and the handling or other preparation of livestock for ritual slaughter are exempted from the terms of this Act. For the purposes of this section the term 'ritual slaughter' means slaughter in accordance with section 2(b) of the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1902(b)).''

## § 604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection

For the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all cattle, sheep, swine, goats, horses, mules, and other equines to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food; and the carcasses and parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as ''Inspected and passed''; and said inspectors shall label, mark, stamp, or tag as ''Inspected and condemned'' all carcasses and parts thereof of animals found to be adulterated; and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection, shall, when they deem it necessary, reinspect said carcasses or parts thereof to determine whether since the first inspection the same have become adulterated, and if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any establishment which fails to so destroy any such condemned carcass or part thereof.

(Mar. 4, 1907, ch. 2907, title I, § 4, formerly 2nd par., 34 Stat. 1260; renumbered § 4 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3, 4, 12(a)–(d), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 72 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3, 4, 12(a)–(d), struck out ''interstate or foreign'' before ''commerce'' and ''of Agriculture'' after ''Secretary'' in three places; struck out ''for human consumption'' before ''at any slaughtering'' and ''for transportation or sale'' after ''District of Columbia'' and inserted ''which are capable of use as human food'' after ''commerce''; included horses, mules, and other equines in the list of animals; substituted ''adulterated'' for ''unsound, unhealthful, unwholesome, or otherwise unfit for human food'' after ''Inspected and condemned,' all carcasses and parts thereof of animals found to be'' and before '', it shall be destroyed''; substituted ''not adulterated'' for ''sound, healthful, wholesome, and fit for human food''; and substituted ''adulterated'' for ''unsound, unhealthful, unwholesome, or in any way unfit for human food'' before ''and if any carcass'', respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

## § 605. Examination of carcasses brought into slaughtering or packing establishments, and of meat food products issued from and returned thereto; conditions for entry

The foregoing provisions shall apply to all carcasses or parts of carcasses of cattle, sheep, swine, goats, horses, mules, and other equines or the meat or meat products thereof which may be brought into any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and such examination and inspection shall be had before the said carcasses or parts thereof shall be allowed to enter into any department wherein the same are to be treated and prepared for meat food products; and the foregoing provisions shall also apply to all such products, which, after having been issued from any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, shall be returned to the same or to any similar establishment where such inspection is maintained. The Secretary may limit the entry of carcasses, parts of carcasses, meat and meat food products, and other materials into any establishment at which inspection under this subchapter is maintained, under such conditions as he may prescribe to assure that allowing the entry of such articles into such inspected establishments will be consistent with the purposes of this chapter.

(Mar. 4, 1907, ch. 2907, title I, § 5, formerly 3rd par., 34 Stat. 1261; renumbered § 5 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 5, 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 73 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 5, 12(a), limited entry of articles into establishments under such prescribed conditions as would be consistent with the purpose of this chapter and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

## § 606. Inspectors of meat food products; marks of inspection; destruction of condemned products; products for export

For the purposes hereinbefore set forth the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection and inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; and said inspectors shall mark, stamp, tag, or label as ''Inspected and passed'' all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as ''Inspected and condemned'' all such products found adulterated, and all such condemned meat food products shall be destroyed for food purposes, as hereinbefore provided, and the Secretary may remove inspectors from any establishment which fails to so destroy such condemned meat food products: *Provided*, That subject to the rules and regulations of the Secretary the provisions of this section in regard to preservatives shall not apply to meat food products for export to any foreign country and which are prepared or packed according to the specifications or directions of the foreign purchaser, when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is to be exported; but if said article shall be in fact sold or offered for sale for domestic use or consumption then this proviso shall not exempt said article from the operation of all the other provisions of this chapter.

(Mar. 4, 1907, ch. 2907, title I, § 6, formerly 4th par., 34 Stat. 1261; renumbered § 6 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3, 12(e), 81 Stat. 584, 588, 592; Nov. 10, 1986, Pub. L. 99–641, title IV, § 403(a), 100 Stat. 3567.)

### CODIFICATION

Section was formerly classified to section 74 of this title.

### AMENDMENTS

1986—Pub. L. 99–641 temporarily added subsecs. (a) to (c) and struck out former undesignated provisions which read as follows: ''For the purposes hereinbefore set forth the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection and inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; and said inspectors shall mark, stamp, tag, or label as 'Inspected and passed' all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as 'Inspected and condemned' all such products found adulterated, and all such condemned meat food products shall be destroyed for food purposes, as hereinbefore provided, and the Secretary may remove inspectors from any establishment which fails to so destroy such condemned meat food products: *Provided*, That'', designated remaining provisions as subsec. (d), and inserted ''Notwithstanding the preceding provisions of this section,''. See Effective and Termination Dates of 1986 Amendment note below.

1967—Pub. L. 90–201, §§ 3, 12(e), struck out ''interstate or foreign'' before ''commerce'' and ''of Agriculture'' after ''Secretary'' in three places, and substituted ''not adulterated'' for ''sound, healthful, and wholesome, and which contains no dyes, chemicals, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food'' and ''adulterated'' for ''unsound, unhealthful, and unwholesome, or which contain dyes, chemicals, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food,'' respectively.

### EFFECTIVE AND TERMINATION DATES OF 1986 AMENDMENT

Section 403(a) of Pub. L. 99–641 provided in part that the amendment of this section by Pub. L. 99–641 is effective only during the 6-year period beginning Nov. 10, 1986.

Section 408 of title IV of Pub. L. 99–641 provided that:

''(a) GENERAL EFFECTIVE DATE.—Except as provided in subsection (b) of this section, this title and the amendments made by this title [amending sections 606, 609, 621, 671, and 676 of this title and enacting provisions set out as notes under sections 606, 609, 621, 671, and 676 of this title] shall become effective on the date of the enactment of this Act [Nov. 10, 1986].

''(b) TEMPORARY APPLICATION OF EXISTING LAW.—Sections 6, 9, and 21 of the Federal Meat Inspection Act (21 U.S.C. 606, 609, and 621), as in effect immediately before the date of the enactment of this Act [Nov. 10, 1986], shall apply with respect to establishments until the Secretary of Agriculture first issues rules and regulations to implement the amendments made by section 403(a) [amending this section].''

### EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### SAVINGS PROVISION

Section 404 of Pub. L. 99–641 provided that: ''The expiration date provisions of section 403 [enacting provisions set out as notes under this section and sections 609, 621, 671, and 676 of this title] shall not have the effect of releasing or extinguishing any penalty, forfeiture, or liability incurred under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), as amended by section 403 [amending this section and sections 609, 621, 671, and 676 of this title], or under the rules or regulations issued under such Act.''

### INSPECTION SERVICES FOR ESTABLISHMENTS NOT PARTICIPATING IN TOTAL PLANT QUALITY-CONTROL PROGRAM

Section 403(e) of Pub. L. 99–641 provided that: ''The amendments made by this section [amending this section and sections 609, 621, 671, and 676 of this title] shall not be construed to authorize the Secretary of Agriculture to refuse to provide inspection under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) at an establishment solely because such establishment does not participate in a total plant quality-control program.''

### DETECTION OF RESIDUE IN LIVESTOCK AND PROGRAM FOR TRACING OF LIVESTOCK

Section 405 of Pub. L. 99–641 provided that: ''It is the sense of Congress that the Secretary of Agriculture should—

''(1) carry out a program to detect residues in livestock that are subject to inspection under title I of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.); and

''(2) evaluate the feasibility of, and develop, a program that would enable the Secretary to trace any particular livestock that are subject to inspection under title I of the Federal Meat Inspection Act, in order to identify the producer of such livestock.''

REPORTS TO CONGRESS

Section 406 of Pub. L. 99–641 provided that: ''Not later than 1 year after the date of the enactment of this Act [Nov. 10, 1986], and annually thereafter, the Secretary of Agriculture shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

''(1) any action proposed or taken by the Secretary to implement the amendments made by section 403 [amending this section and sections 609, 621, 671, and 676 of this title];

''(2) any action proposed or taken by the Secretary to carry out a program to detect residues in livestock that are subject to inspection under title I of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);

''(3) any action proposed or taken by the Secretary to evaluate the feasibility of, and develop, a program that would enable the Secretary to trace any particular livestock that are subject to inspection under such title, in order to identify the producer of such livestock; and

''(4) any personnel action proposed or taken by the Secretary as a result of the amendments made by section 403 and any effort made by the Secretary to minimize any adverse economic effect of such amendments on employees of the Department of Agriculture.''

CONGRESSIONAL REEVALUATION OF INSPECTION PROGRAM

Section 407 of Pub. L. 99–641 provided that: ''It is the sense of Congress that, not later than 6 years after the date of the enactment of this Act [Nov. 10, 1986], Congress shall—

''(1) evaluate the operation and effects of the amendments made by section 403 [amending this section and sections 609, 621, 671, and 676 of this title], for the purpose of determining whether to extend or modify the operation of such amendments; and

''(2) enact such legislation as may be necessary to efficiently and effectively carry out the Federal Meat Inspection Act (21 U.S.C. 601 et seq.).''

## § 607. Labeling, marking, and container requirements

### (a) Labeling receptacles or coverings of meat or meat food products inspected and passed; supervision by inspectors

When any meat or meat food product prepared for commerce which has been inspected as hereinbefore provided and marked ''Inspected and passed'' shall be placed or packed in any can, pot, tin, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained, the person, firm, or corporation preparing said product shall cause a label to be attached to said can, pot, tin, canvas, or other receptacle or covering, under the supervision of an inspector, which label shall state that the contents thereof have been ''inspected and passed'' under the provisions of this chapter; and no inspection and examination of meat or meat food products deposited or inclosed in cans, tins, pots, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained shall be deemed to be complete until such meat or meat food products have been sealed or inclosed in said can, tin, pot, canvas, or other receptacle or covering under the supervision of an inspector.

### (b) Information on articles or containers; legible form

All carcasses, parts of carcasses, meat and meat food products inspected at any establishment under the authority of this subchapter and found to be not adulterated, shall at the time they leave the establishment bear, in distinctly legible form, directly thereon or on their containers, as the Secretary may require, the information required under paragraph (n) of section 601 of this title.

### (c) Labeling: type styles and sizes; definitions and standards of identity or composition; standards of fill of container; consistency of Federal and Federal-State standards

The Secretary, whenever he determines such action is necessary for the protection of the public, may prescribe: (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling in marketing and labeling any articles or animals subject to this subchapter or subchapter II of this chapter; (2) definitions and standards of identity or composition for articles subject to this subchapter and standards of fill of container for such articles not inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and there shall be consultation between the Secretary and the Secretary of Health and Human Services prior to the issuance of such standards under either Act relating to articles subject to this chapter to avoid inconsistency in such standards and possible impairment of the coordinated effective administration of these Acts. There shall also be consultation between the Secretary and an appropriate advisory committee provided for in section 661 of this title, prior to the issuance of such standards under this chapter, to avoid, insofar as feasible, inconsistency between Federal and State standards.

### (d) Sales under false or misleading name, other marking or labeling or in containers of misleading form or size; trade names, and other marking, labeling, and containers approved by Secretary

No article subject to this subchapter shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.

### (e) Use withholding directive respecting false or misleading marking, labeling, or container; modification of false or misleading matter; hearing; withholding use pending proceedings; finality of Secretary's action; judicial review; application of section 194 of title 7

If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect

to any article subject to this subchapter is false or misleading in any particular, he may direct that such use be withheld unless the marking, labeling, or container is modified in such manner as he may prescribe so that it will not be false or misleading. If the person, firm, or corporation using or proposing to use the marking, labeling or container does not accept the determination of the Secretary, such person, firm, or corporation may request a hearing, but the use of the marking, labeling, or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person, firm, or corporation adversely affected thereby appeals to the United States court of appeals for the circuit in which such person, firm, or corporation has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

(Mar. 4, 1907, ch. 2907, title I, § 7, formerly 5th par., 34 Stat. 1262; renumbered § 7 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(a), 6, 81 Stat. 584, 588; Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

Either Act and these Acts, referred to in subsec. (c)(2), mean the Federal Meat Inspection Act and the Federal Food, Drug, and Cosmetic Act. The Federal Meat Inspection Act is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90–201, 81 Stat. 584, and amended, which are classified generally to subchapters I to IV (§ 601 et seq.), respectively, of this chapter. For complete classification of this Act to the Code, see Short Title note under section 601 of this title and Tables.

CODIFICATION

Section was formerly classified to section 75 of this title.

AMENDMENTS

1967—Subsec. (a). Pub. L. 90–201, §§ 3(a), 6(a), (b), struck out ''interstate or foreign'' before ''commerce'' and provisions prohibiting sales of meat or meat food products in interstate or foreign commerce under any false or deceptive names and permitting trade names or names which are usual to such products and are not false and deceptive and are approved by the Secretary of Agriculture, now incorporated in subsec. (d), and designated remaining provisions as subsecs. (a), respectively.

Subsecs. (b) to (e). Pub. L. 90–201, § 6(c), added subsecs. (b) to (e).

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsec. (c)(2) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act defined, see section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 601, 674 of this title.

## § 608. Sanitary inspection and regulation of slaughtering and packing establishments; rejection of adulterated meat or meat food products

The Secretary shall cause to be made, by experts in sanitation or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which cattle, sheep, swine, goats, horses, mules and other equines are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the sanitary conditions of the same, and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained; and where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped or tagged as ''inspected and passed.''

(Mar. 4, 1907, ch. 2907, title I, § 8, formerly 6th par., 34 Stat. 1262; renumbered § 8 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3, 12(a), (f), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 76 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3, 12(a), (f), struck out ''interstate or foreign'' before ''commerce'' and ''of Agriculture'' after ''Secretary'', included horses, mules, and other equines in the list of animals, and substituted ''adulterated'' for ''unclean, unsound, unhealthful, unwholesome, or otherwise unfit for human food'', respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

## § 609. Examination of animals and food products thereof, slaughtered and prepared during nighttime

The Secretary shall cause an examination and inspection of all cattle, sheep, swine, goats, horses, mules and other equines, and the food products thereof, slaughtered and prepared in the establishments hereinbefore described for the purposes of commerce to be made during the nighttime as well as during the daytime when

the slaughtering of said cattle, sheep, swine, goats, horses, mules, and other equines, or the preparation of said food products is conducted during the nighttime.

(Mar. 4, 1907, ch. 2907, title I, § 9, formerly 7th par., 34 Stat. 1262; renumbered § 9 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3, 12(a), 81 Stat. 584, 588, 592; Nov. 10, 1986, Pub. L. 99–641, title IV, § 403(d)(1), 100 Stat. 3570.)

CODIFICATION

Section was formerly classified to section 77 of this title.

AMENDMENTS

1986—Pub. L. 99–641 temporarily inserted ", except as provided in section 606 of this title," after first reference to "other equines, and". See Effective and Termination Dates of 1986 Amendment note below.

1967—Pub. L. 90–201, §§ 3, 12(a), struck out "interstate or foreign" before "commerce" and "of Agriculture" after "Secretary" and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE AND TERMINATION DATES OF 1986 AMENDMENT

Section 403(d)(1) of Pub. L. 99–641 provided that the amendment made by that section is effective only during the 6-year period beginning Nov. 10, 1986.

Amendment by Pub. L. 99–641 effective Nov. 10, 1986, except that this section as in effect immediately before Nov. 10, 1986, applies with respect to establishments until the Secretary of Agriculture first issues rules and regulations to implement the amendments made by section 403(a) of Pub. L. 99–641 to section 606 of this title, see section 408 of Pub. L. 99–641, set out as a note under section 606 of this title.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

CONSTRUCTION AND EFFECT OF AMENDMENTS BY PUB. L. 99–641

For provisions relating to construction and effect of temporary amendments by section 403 of Pub. L. 99–641, see sections 403(e) and 404 of Pub. L. 99–641, set out as notes entitled "Inspection Services for Establishments Not Participating in Total Plant Quality-Control Program" and "Savings Provision", respectively, under section 606 of this title.

## § 610. Prohibited acts

No person, firm, or corporation shall, with respect to any cattle, sheep, swine, goats, horses, mules, or other equines, or any carcasses, parts of carcasses, meat or meat food products of any such animals—

**(a) Slaughtering animals or preparation of articles capable of use as human food**

slaughter any such animals or prepare any such articles which are capable of use as human food at any establishment preparing any such articles for commerce, except in compliance with the requirements of this chapter;

**(b) Humane methods of slaughter**

slaughter or handle in connection with slaughter any such animals in any manner not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901–1906);

**(c) Sales, transportation, and other transactions**

sell, transport, offer for sale or transportation, or receive for transportation, in commerce, (1) any such articles which (A) are capable of use as human food and (B) are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation; or (2) any articles required to be inspected under this subchapter unless they have been so inspected and passed;

**(d) Adulteration or misbranding**

do, with respect to any such articles which are capable of use as human food, any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such articles to be adulterated or misbranded.

(Mar. 4, 1907, ch. 2907, title I, § 10, formerly 8th par., 34 Stat. 1262; renumbered § 10 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 7, 81 Stat. 584, 589; Oct. 10, 1978, Pub. L. 95–445, § 3, 92 Stat. 1069.)

REFERENCES IN TEXT

Act of August 27, 1958, referred to in subsec. (b), is Pub. L. 85–765, Aug. 27, 1958, 72 Stat. 862, as amended, which is classified generally to chapter 48 (§ 1901 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Tables.

Sections 1903 and 1905 of Title 7, included within reference to Act of August 27, 1958, were repealed by Pub. L. 95–445, § 5(b), Oct. 10, 1978, 92 Stat. 1069, effective as set forth in section 7 of Pub. L. 95–445, set out as an Effective Date of 1978 Amendment note under section 603 of this title.

CODIFICATION

Section was formerly classified to section 78 of this title.

AMENDMENTS

1978—Subsecs. (b) to (d). Pub. L. 95–445 added subsec. (b) and redesignated former subsecs. (b) and (c) as (c) and (d), respectively.

1967—Pub. L. 90–201, § 7, included the list of animals and prohibited, except in compliance with requirements of this chapter, slaughtering animals or preparation of articles capable of use as human food, sales, transportation, and other transactions, and acts of adulteration or misbranding, incorporating in subsec. (b)(2) existing prohibition on distributions in interstate or foreign commerce of noninspected articles.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–445 effective one year after Oct. 10, 1978, and an additional eighteen month period thereafter in hardship cases, see section 7 of Pub. L. 95–445, set out as an Effective Date of 1978 Amendment note under section 603 of this title.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that subsecs. (b)(1) and (c) of this section effective upon expiration of sixty days after Dec. 15, 1967, see section 20(a) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### § 611. Devices, marks, labels, and certificates; simulations

#### (a) Devices to be made under authorization of Secretary

No brand manufacturer, printer, or other person, firm, or corporation shall cast, print, lithograph, or otherwise make any device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, or any form of official certificate or simulation thereof, except as authorized by the Secretary.

#### (b) Other misconduct

No person, firm, or corporation shall—

(1) forge any official device, mark, or certificate;

(2) without authorization from the Secretary use any official device, mark, or certificate, or simulation thereof, or alter, detach, deface, or destroy any official device, mark, or certificate;

(3) contrary to the regulations prescribed by the Secretary, fail to use, or to detach, deface, or destroy any official device, mark, or certificate;

(4) knowingly possess, without promptly notifying the Secretary or his representative, any official device or any counterfeit, simulated, forged, or improperly altered official certificate or any device or label or any carcass of any animal, or part or product thereof, bearing any counterfeit, simulated, forged, or improperly altered official mark;

(5) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary; or

(6) knowingly represent that any article has been inspected and passed, or exempted, under this chapter when, in fact, it has, respectively, not been so inspected and passed, or exempted.

(Mar. 4, 1907, ch. 2907, title I, § 11, formerly 9th par., 34 Stat. 1263; renumbered § 11 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 8, 81 Stat. 584, 589.)

CODIFICATION

Section was formerly classified to section 79 of this title.

AMENDMENTS

1967—Pub. L. 90–201, § 8, clarified application to brand manufacturers and printers of existing prohibition against counterfeiting official marks, labels or certificates, the provisions with respect to forgery, unauthorized use or failure to use official marks, or similar items, and similar offenses, and existing prohibitions with respect to false statements in official or nonofficial certificates, and added restriction upon possession of official devices, or devices, labels, meat, or other articles bearing counterfeit official marks, counterfeit official certificates, or similar items, and prohibition against false representations.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### § 612. Inspection of animals for export

The Secretary shall cause to be made a careful inspection of all cattle, sheep, swine, goats, horses, mules, and other equines intended and offered for export to foreign countries at such times and places, and in such manner as he may deem proper, to ascertain whether such cattle, sheep, swine, goats, horses, mules, and other equines are free from disease.

(Mar. 4, 1907, ch. 2907, title I, § 12, formerly 10th par., 34 Stat. 1263; renumbered § 12 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 80 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3(b), 12(a), struck out "of Agriculture" after "Secretary" and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 613 of this title; title 16 section 1540.

### § 613. Inspectors of animals for export; certificates of condition

For the purpose of section 612 of this title the Secretary may appoint inspectors who shall be authorized to give an official certificate clearly stating the condition in which such cattle, sheep, swine, goats, horses, mules, and other equines are found.

(Mar. 4, 1907, ch. 2907, title I, § 13, formerly 11th par., 34 Stat. 1263; renumbered § 13 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 81 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3(b), 12(a), struck out "of Agriculture" after "Secretary", and included horses, mules, and other equines in the list of animals.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

### § 614. Clearance prohibited to vessel carrying animals for export without inspector's certificate

No clearance shall be given to any vessel having on board cattle, sheep, swine, goats, horses,

mules, or other equines for export to a foreign country until the owner or shipper of such cattle, sheep, swine, goats, horses, mules, or other equines has a certificate from the inspector authorized to be appointed, stating that the said cattle, sheep, swine, goats, horses, mules, or other equines are sound and healthy, or unless the Secretary shall have waived the requirement of such certificate for export to the particular country to which such cattle, sheep, swine, goats, horses, mules, or other equines are to be exported.

(Mar. 4, 1907, ch. 2907, title I, § 14, formerly 12th par., 34 Stat. 1263; renumbered § 14 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 82 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3(b), 12(a), struck out ''of Agriculture'' after ''Secretary'' and included horses, mules, or other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

## § 615. Inspection of carcasses, meat of which is intended for export

The Secretary shall also cause to be made a careful inspection of the carcasses and parts thereof of all cattle, sheep, swine, goats, horses, mules, and other equines, the meat of which, fresh, salted, canned, corned, packed, cured, or otherwise prepared, is intended and offered for export to any foreign country, at such times and places and in such manner as he may deem proper.

(Mar. 4, 1907, ch. 2907, title I, § 15, formerly 13th par., 34 Stat. 1263; renumbered § 15 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 83 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3(b), 12(a), struck out ''of Agriculture'' after ''Secretary'' and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 616 of this title.

## § 616. Inspectors of carcasses, etc., meat of which is intended for export; certificates of condition

For the purpose of section 615 of this title the Secretary may appoint inspectors who shall be authorized to give an official certificate stating the condition in which said cattle, sheep, swine, goats, horses, mules, or other equines, and the meat thereof, are found.

(Mar. 4, 1907, ch. 2907, title I, § 16, formerly 14th par., 34 Stat. 1263; renumbered § 16 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 84 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3(b), 12(a), struck out ''of Agriculture'' after ''Secretary'', and included horses, mules, or other equines in the list of animals.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

## § 617. Clearance prohibited to vessel carrying meat for export without inspector's certificate

No clearance shall be given to any vessel having on board any fresh, salted, canned, corned, or packed beef, mutton, pork, goat or equine meat for export to and sale in a foreign country from any port in the United States, until the owner or shipper thereof shall obtain from an inspector appointed under the provisions of this chapter a certificate that the said cattle, sheep, swine, goats, horses, mules, and other equines were sound and healthy at the time of inspection, and that their meat is sound and wholesome, unless the Secretary shall have waived the requirements of such certificate for the country to which said cattle, sheep, swine, goats, horses, mules, and other equines or meats are to be exported.

(Mar. 4, 1907, ch. 2907, title I, § 17, formerly 15th par., 34 Stat. 1263; renumbered § 17 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(b), 12(a), (g), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 85 of this title.

AMENDMENTS

1967—Pub. L. 90–201, §§ 3(b), 12(a), (g), struck out ''of Agriculture'' after ''Secretary'', included horses, mules, and other equines in the list of animals, and substituted ''goat or equine meat'' for ''or goat meat, being the meat of animals killed after March 4, 1907, or except as hereinbefore provided'', respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat

food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### § 618. Delivery of inspectors' certificates, and of copies

The inspectors provided for under this subchapter shall be authorized to give official certificates of the condition of the cattle, sheep, swine, goats, horses, mules, and other equines, their carcasses and products as described in this subchapter; and one copy of every certificate granted under the provisions of this chapter shall be filed in the Department of Agriculture, another copy shall be delivered to the owner or shipper, and when the cattle, sheep, swine, goats, horses, mules, and other equines, or their carcasses and products are sent abroad, a third copy shall be delivered to the chief officer of the vessel on which the shipment shall be made.

(Mar. 4, 1907, ch. 2907, title I, § 18, formerly 16th par., 34 Stat. 1263; renumbered § 18 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 12(a), (h), 81 Stat. 584, 592.)

CODIFICATION

"Provided for under this subchapter", and "described in this subchapter" was in the original "provided for herein" and "herein described", respectively.

Section was formerly classified to section 86 of this title.

AMENDMENTS

1967—Pub. L. 90–201, § 12(a), (h), included horses, mules, and other equines in the list of animals and struck out "sound and wholesome" before "conditions", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### § 619. Marking, labeling, or other identification of kinds of animals of articles' derivation; separate establishments for preparation and slaughtering activities

No person, firm, or corporation shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any carcasses of horses, mules, or other equines or parts of such carcasses, or the meat or meat food products thereof, unless they are plainly and conspicuously marked or labeled or otherwise identified as required by regulations prescribed by the Secretary to show the kinds of animals from which they were derived. When required by the Secretary, with respect to establishments at which inspection is maintained under this subchapter, such animals and their carcasses, parts thereof, meat and meat food products shall be prepared in establishment separate from those in which cattle, sheep, swine, or goats are slaughtered or their carcasses, parts thereof, meat or meat food products are prepared.

(Mar. 4, 1907, ch. 2907, title I, § 19, formerly 17th par., 34 Stat. 1264; renumbered § 19 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 9, 81 Stat. 584, 590.)

CODIFICATION

Section was formerly classified to section 87 of this title.

AMENDMENTS

1967—Pub. L. 90–201, § 9, substituted provisions for marking, labeling, or other identification of kinds of animals whence the articles are derived and for separate establishments for preparation and slaughtering activities for prohibition against transportation or sale of meat or meat food products without complying with inspection provisions. See section 610(b) of this title.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration, of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### § 620. Imports

#### (a) Adulteration or misbranding prohibition; compliance with inspection, building construction standards, and other provisions; humane methods of slaughter; treatment as domestic articles subject to this chapter and food, drug, and cosmetic provisions; marking and labeling; personal consumption exemption

No carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food, shall be imported into the United States if such articles are adulterated or misbranded and unless they comply with all the inspection, building, construction standards, and all other provisions of this chapter and regulations issued thereunder applicable to such articles in commerce within the United States. No such carcasses, parts of carcasses, meat or meat food products shall be imported into the United States unless the livestock from which they were produced was slaughtered and handled in connection with slaughter in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901–1906). All such imported articles shall, upon entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]: *Provided*, That they shall be marked and labeled as required by such regulations for imported articles: *Provided further*, That nothing in this section shall apply to any individual who purchases meat or meat products outside the United States for his own consumption except that the total amount of such meat or meat products shall not exceed fifty pounds.

#### (b) Terms and conditions for destruction

The Secretary may prescribe the terms and conditions for the destruction of all such articles which are imported contrary to this section, unless (1) they are exported by the consignee within the time fixed therefor by the Secretary, or (2) in the case of articles which are not in compliance with the chapter solely be-

cause of misbranding, such articles are brought into compliance with the chapter under supervision of authorized representatives of the Secretary.

**(c) Payment of storage, cartage, and labor charges by owner or consignee; liens**

All charges for storage, cartage, and labor with respect to any article which is imported contrary to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such article and any other article thereafter imported under this chapter by or for such owner or consignee.

**(d) Prohibition**

The knowing importation of any article contrary to this section is prohibited.

**(e) Reports to Congressional committees**

Not later than March 1 of each year the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a comprehensive and detailed written report with respect to the administration of this section during the immediately preceding calendar year. Such report shall include, but shall not be limited to the following:

(1)(A) A certification by the Secretary that foreign plants exporting carcasses or meat or meat products referred to in subsection (a) of this section have complied with requirements that achieve a level of sanitary protection equivalent to that achieved under United States requirements with regard to all inspection, building construction standards, and all other provisions of this chapter and regulations issued under this chapter.

(B) The Secretary may treat as equivalent to a United States requirement a requirement described in subparagraph (A) if the exporting country provides the Secretary with scientific evidence or other information, in accordance with risk assessment methodologies determined appropriate by the Secretary, to demonstrate that the requirement achieves the level of sanitary protection achieved under the United States requirement. For the purposes of this subsection, the term ''sanitary protection'' means protection to safeguard public health.

(C) The Secretary may—

(i) determine, on a scientific basis, that a requirement of an exporting country does not achieve the level of protection that the Secretary considers appropriate; and

(ii) provide the basis for the determination to the exporting country in writing on request.

(2) The names and locations of plants authorized or permitted to have imported into the United States therefrom carcasses or meat or meat products referred to in subsection (a) of this section.

(3) The number of inspectors employed by the Department of Agriculture in the calendar year concerned who were assigned to inspect plants referred to in paragraph (e)(2)[1] hereof and the frequency with which each such plant was inspected by such inspectors.

(4) The number of inspectors licensed by each country from which any imports subject to the provisions of this section were imported who were assigned, during the calendar year concerned, to inspect such imports and the facilities in which such imports were handled and the frequency and effectiveness of such inspections.

(5) The total volume of carcasses or meat or meat products referred to in subsection (a) of this section which was imported into the United States during the calendar year concerned from each country, including a separate itemization of the volume of each major category of such imports from each country during such year, and a detailed report of rejections of plants and products because of failure to meet appropriate standards prescribed by this chapter.

(6) The name of each foreign country that applies standards for the importation of meat articles from the United States that are described in subsection (h)(2) of this section.

**(f) Inspection and other standards; applicability, enforcement, etc.; certifications**

Notwithstanding any other provision of law, all carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, offered for importation into the United States shall be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States. Any such imported meat articles that do not meet such standards shall not be permitted entry in to the United States. The Secretary shall enforce this provision through (1) the imposition of random inspections for such species verification and for residues, and (2) random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country in accordance with methods approved by the Secretary. Each foreign country from which such meat articles are offered for importation into the United States shall obtain a certification issued by the Secretary stating that the country maintains a program using reliable analytical methods to ensure compliance with the United States standards for residues in such meat articles. No such meat article shall be permitted entry into the United States from a country for which the Secretary has not issued such certification. The Secretary shall periodically review such certifications and shall revoke any certification if the Secretary determines that the country involved is not maintaining a program that uses reliable analytical methods to ensure compliance with United States standards for residues in such meat articles. The consideration of any application for a certification under this subsection and the review of any such certification, by the Secretary, shall include the inspection of individual establishments to ensure that the inspection program of the foreign country involved is meeting such United States standards.

[1] See References in Text note below.

**(g) Administration of animal drugs or antibiotics; terms and conditions; entry order violations**

The Secretary may prescribe terms and conditions under which cattle, sheep, swine, goats, horses, mules, and other equines that have been administered an animal drug or antibiotic banned for use in the United States may be imported for slaughter and human consumption. No person shall enter cattle, sheep, swine, goats, horses, mules, and other equines into the United States in violation of any order issued under this subsection by the Secretary.

**(h) Reciprocal meat inspection requirement**

(1) As used in this subsection:

(A) The term ''meat articles'' means carcasses, meat and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, that are capable of use as human food.

(B) The term ''standards'' means inspection, building construction, sanitary, quality, species verification, residue, and other standards that are applicable to meat articles.

(2) On request of the Committee on Agriculture or the Committee on Ways and Means of the House of Representatives or the Committee on Agriculture, Nutrition, and Forestry or the Committee on Finance of the Senate, or at the initiative of the Secretary, the Secretary shall, as soon as practicable, determine whether a particular foreign country applies standards for the importation of meat articles from the United States that are not related to public health concerns about end-product quality that can be substantiated by reliable analytical methods.

(3) If the Secretary determines that a foreign country applies standards described in paragraph (2)—

(A) the Secretary shall consult with the United States Trade Representative; and

(B) within 30 days after the determination of the Secretary under paragraph (2), the Secretary and the United States Trade Representative shall recommend to the President whether action should be taken under paragraph (4).

(4) Within 30 days after receiving a recommendation for action under paragraph (3), the President shall, if and for such time as the President considers appropriate, prohibit imports into the United States of any meat articles produced in such foreign country unless it is determined that the meat articles produced in that country meet the standards applicable to meat articles in commerce within the United States.

(5) The action authorized under paragraph (4) may be used instead of, or in addition to, any other action taken under any other law.

(Mar. 4, 1907, ch. 2907, title I, § 20, formerly 18th par., 34 Stat. 1264; renumbered § 20 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 10, 81 Stat. 584, 590; Oct. 10, 1978, Pub. L. 95–445, § 4, 92 Stat. 1069; Dec. 22, 1981, Pub. L. 97–98, title XI, § 1122, 95 Stat. 1273; Dec. 23, 1985, Pub. L. 99–198, title XVII, § 1702, 99 Stat. 1634; Aug. 23, 1988, Pub. L. 100–418, title IV, § 4604, 102 Stat. 1408; Dec. 8, 1993, Pub. L. 103–182, title III, § 361(f), 107 Stat. 2124; Nov. 2, 1994, Pub. L. 103–437, § 8(2), 108 Stat. 4588; Dec. 8, 1994, Pub. L. 103–465, title IV, § 431(*l*), 108 Stat. 4970.)

REFERENCES IN TEXT

Act of August 27, 1958, referred to in subsec. (a), is Pub. L. 85–765, Aug. 27, 1958, 72 Stat. 862, as amended, which is classified generally to chapter 48 (§ 1901 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Tables.

Sections 1903 and 1905 of Title 7, included within reference to Act of August 27, 1958, were repealed by Pub. L. 95–445, § 5(b), Oct. 10, 1978, 92 Stat. 1069, effective as set forth in section 7 of Pub. L. 95–445, set out as an Effective Date of 1978 Amendment note under section 603 of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this act to the Code, see section 301 of this title and Tables.

Paragraph (e)(2), referred to in par. (e)(3), was struck out and pars. (e)(3) to (e)(7) were redesignated (e)(2) to (e)(6), respectively, by Pub. L. 103–465.

CODIFICATION

Section was formerly classified to section 88 of this title.

AMENDMENTS

1994—Subsec. (e). Pub. L. 103–437 substituted ''Agriculture, Nutrition, and Forestry'' for ''Agriculture and Forestry'' in introductory provisions.

Subsec. (e)(1)(A), (B). Pub. L. 103–465, § 431(*l*)(1), amended subpars. (A) and (B) generally. Prior to amendment, subpars. (A) and (B) read as follows:

''(A) Subject to subparagraphs (B) and (C), a certification by the Secretary that foreign plants in Canada and Mexico that export carcasses or meat or meat products referred to in subsection (a) of this section have complied with paragraph (2) or with requirements that are equivalent to United States requirements with regard to all inspection and building construction standards, and all other provisions of this chapter and regulations issued under this chapter.

''(B) Subject to subparagraph (C), the Secretary may treat as equivalent to a United States requirement a requirement described in subparagraph (A) if the exporting country provides the Secretary with scientific evidence or other information, in accordance with risk assessment methodologies agreed to by the Secretary and the exporting country, to demonstrate that the requirement or standard of the exporting country achieves the level of protection that the Secretary considers appropriate.''

Subsec. (e)(2) to (7). Pub. L. 103–465, § 431(*l*)(2), (3), redesignated pars. (3) to (7) as (2) to (6), respectively, and struck out former par. (2) which read as follows: ''A certification by the Secretary that, except as provided in paragraph (1), foreign plants that export carcasses or meat or meat products referred to in subsection (a) of this section have complied with requirements that are at least equal to all inspection and building construction standards and all other provisions of this chapter and regulations issued under this chapter.''

1993—Subsec. (e). Pub. L. 103–182, § 361(f)(1), substituted ''not be limited to the following:'' for ''not be limited to—'' in introductory provisions.

Subsec. (e)(1) to (7). Pub. L. 103–182, § 361(f)(2)–(7), added pars. (1) and (2), struck out former par. (1), redesignated pars. (2) to (6) as (3) to (7), respectively, substituted ''The'' for ''the'' at beginning of each par., substituted period for semicolon at end of pars. (3) to (5), and substituted period for ''; and'' at end of par. (6). Prior to amendment, former par. (1) read as follows: ''a certification by the Secretary that foreign plants exporting carcasses or meat or meat products referred to in subsection (a) of this section have complied with re-

quirements at least equal to all the inspection, building construction standards, and all other provisions of this chapter and regulations issued thereunder;''.

1988—Subsec. (e)(6). Pub. L. 100–418, § 4604(b), added par. (6).

Subsec. (h). Pub. L. 100–418, § 4604(a), added subsec. (h).

1985—Subsec. (f). Pub. L. 99–198, § 1702(a), struck out provision which had made this subsection effective six months after Dec. 22, 1981, and inserted provisions requiring that each foreign country from which meat articles are offered for importation into the United States obtain a certification issued by the Secretary stating that the country maintains a program using reliable analytical methods to ensure compliance with the United States standards for residues in such meat articles, that no meat article be permitted entry into the United States from a country for which the Secretary has not issued such certification, that the Secretary periodically review such certifications and revoke any certification if the Secretary determines that the country involved is not maintaining a program that uses reliable analytical methods to ensure compliance with United States standards for residues in such meat articles, and that the consideration of any application for a certification under this subsection and the review of any such certification, by the Secretary, include the inspection of individual establishments to ensure that the inspection program of the foreign country involved is meeting such United States standards.

Subsec. (g). Pub. L. 99–198, § 1702(b), added subsec. (g).

1981—Subsec. (f). Pub. L. 97–98 added subsec. (f).

1978—Subsec. (a). Pub. L. 95–445 prohibited imports which do not comply with humane methods of slaughter.

1967—Pub. L. 90–201, § 10, substituted imported articles provisions for penalty provisions deeming offenses as misdemeanors and punishable by fine of $10,000 or imprisonment for two years or both. See section 676(a) of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective, except as otherwise provided, on the date of entry into force of the World Trade Organization Agreement with respect to the United States [Jan. 1, 1995], see section 451 of Pub. L. 103–465, set out as an Effective Date note under section 3601 of Title 19, Customs Duties.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–98 effective Dec. 22, 1981, see section 1801 of Pub. L. 97–98, set out as an Effective Date note under section 4301 of Title 7, Agriculture.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–445 effective one year after Oct. 10, 1978, and an additional eighteen-month period thereafter in hardship cases, see section 7 of Pub. L. 95–445, set out as a note under section 603 of this title.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective upon expiration of sixty days after Dec. 15, 1967, see section 20(a) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act defined, see section 601 of this title.

## § 621. Inspectors to make examinations provided for; appointment; duties; regulations

The Secretary shall appoint from time to time inspectors to make examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines, inspection of which is hereby provided for and of all carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which such meat and meat food products hereinbefore described are prepared; and said inspectors shall refuse to stamp, mark, tag, or label any carcass or any part thereof, or meat food product therefrom, prepared in any establishment hereinbefore mentioned, until the same shall have actually been inspected and found to be not adulterated; and shall perform such other duties as are provided by this chapter and by the rules and regulations to be prescribed by said Secretary; and said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter, and all inspections and examinations made under this chapter, shall be such and made in such manner as described in the rules and regulations prescribed by said Secretary not inconsistent with provisions of this chapter.

(Mar. 4, 1907, ch. 2907, title I, § 21, formerly 19th par., 34 Stat. 1264; renumbered § 21 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3(b), 12(a), (i), 81 Stat. 584, 588, 592, 593; Nov. 10, 1986, Pub. L. 99–641, title IV, § 403(d)(2), 100 Stat. 3570.)

CODIFICATION

Section was formerly classified to section 89 of this title.

AMENDMENTS

1986—Pub. L. 99–641 temporarily substituted ''thereof, and of meat food products'' for ''and meat food products'', which substitution was made for the first such reference as the probable intent of Congress. See Effective and Termination Dates of 1986 Amendment note below.

1967—Pub. L. 90–201, §§ 3(b), 12(a), (i), struck out ''of Agriculture'' after ''Secretary'' in four places, included horses, mules, and other equines in the list of animals, and substituted ''not adulterated'' for ''sound, healthful, wholesome, and fit for human food, and to contain no dyes, chemicals, preservatives, or ingredients which render such meat food product unsound, unhealthful, unwholesome, or unfit for human food; and to have been prepared under proper sanitary conditions, hereinbefore provided for'', respectively.

EFFECTIVE AND TERMINATION DATES OF 1986 AMENDMENT

Section 403(d)(2) of Pub. L. 99–641 provided that the amendment made by that section is effective only during the 6-year period beginning on Nov. 10, 1986.

Amendment by Pub. L. 99–641 effective Nov. 10, 1986, except that this section as in effect immediately before Nov. 10, 1986, applies with respect to establishments until the Secretary of Agriculture first issues rules and regulations to implement the amendments made by section 403(a) of Pub. L. 99–641 to section 606 of this title, see section 408 of Pub. L. 99–641, set out as a note under section 606 of this title.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

CONSTRUCTION AND EFFECT OF AMENDMENTS BY PUB. L. 99–641

For provisions relating to construction and effect of temporary amendments by section 403 of Pub. L. 99–641,

see sections 403(e) and 404 of Pub. L. 99–641, set out as notes entitled ''Inspection Services for Establishments Not Participating in Total Plant Quality-Control Program'' and ''Savings Provision'', respectively, under section 606 of this title.

### § 622. Bribery of or gifts to inspectors or other officers and acceptance of gifts

Any person, firm, or corporation, or any agent or employee of any person, firm, or corporation, who shall give, pay, or offer, directly or indirectly, to any inspector, deputy inspector, chief inspector, or any other officer or employee of the United States authorized to perform any of the duties prescribed by this chapter or by the rules and regulations of the Secretary any money or other thing of value, with intent to influence said inspector, deputy inspector, chief inspector, or other officer or employee of the United States in the discharge of any duty provided for in this chapter, shall be deemed guilty of a felony, and, upon conviction thereof, shall be punished by a fine not less than $5,000 nor more than $10,000 and by imprisonment not less than one year nor more than three years; and any inspector, deputy inspector, chief inspector, or other officer or employee of the United States authorized to perform any of the duties prescribed by this chapter who shall accept any money, gift, or other thing of value from any person, firm, or corporation, or officers, agents, or employees thereof, given with intent to influence his official action, or who shall receive or accept from any person, firm, or corporation engaged in commerce any gift, money, or other thing of value, given with any purpose or intent whatsoever, shall be deemed guilty of a felony and shall, upon conviction thereof, be summarily discharged from office and shall be punished by a fine not less than $1,000 nor more than $10,000 and by imprisonment not less than one year nor more than three years.

(Mar. 4, 1907, ch. 2907, title I, § 22, formerly 20th par., 34 Stat. 1264; renumbered § 22 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3, 81 Stat. 584, 588.)

CODIFICATION

Section was formerly classified to section 90 of this title.

AMENDMENTS

1967—Pub. L. 90–201, § 3, struck out ''interstate or foreign'' before ''commerce'' and ''of Agriculture'' after ''Secretary''.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

### § 623. Exemptions from inspection requirements

#### (a) Personal slaughtering and custom slaughtering for personal, household, guest, and employee uses

The provisions of this subchapter requiring inspection of the slaughter of animals and the preparation of the carcasses, parts thereof, meat and meat food products at establishments conducting such operations for commerce shall not apply to the slaughtering by any person of animals of his own raising, and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such animals exclusively for use by him and members of his household and his nonpaying guests and employees; nor to the custom slaughter by any person, firm, or corporation of cattle, sheep, swine or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such animals, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person, firm, or corporation of carcasses, parts thereof, meat or meat food products, derived from the slaughter by any person of cattle, sheep, swine, or goats of his own raising, or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided*, That in cases where such person, firm, or corporation engages in such custom operations at an establishment at which inspection under this subchapter is maintained, the Secretary may exempt from such inspection at such establishment any animals slaughtered or any meat or meat food products otherwise prepared on such custom basis: *Provided further*, That custom operations at any establishment shall be exempt from inspection requirements as provided by this section only if the establishment complies with regulations which the Secretary is hereby authorized to promulgate to assure that any carcasses, parts thereof, meat or meat food products wherever handled on a custom basis, or any containers or packages containing such articles, are separated at all times from carcasses, parts thereof, meat or meat food products prepared for sale, and that all such articles prepared on a custom basis, or any containers or packages containing such articles, are plainly marked ''Not for Sale'' immediately after being prepared and kept so identified until delivered to the owner and that the establishment conducting the custom operation is maintained and operated in a sanitary manner.

#### (b) Territorial exemption; refusal, withdrawal, or modification

The Secretary may, under such sanitary conditions as he may by regulations prescribe, exempt from the inspection requirements of this subchapter the slaughter of animals, and the preparation of carcasses, parts thereof, meat and meat food products, by any person, firm, or corporation in any Territory not organized with a legislative body solely for distribution within such Territory when the Secretary determines that it is impracticable to provide such inspection within the limits of funds appropriated for administration of this chapter and that such exemption will otherwise facilitate enforcement of

this chapter. The Secretary may refuse, withdraw, or modify any exemption under this subsection in his discretion whenever he determines such action is necessary to effectuate the purposes of this chapter.

**(c) Pizzas containing meat food products**

(1) Under such terms and conditions as the Secretary shall prescribe through rules and regulations issued under section 624 of this title that may be necessary to ensure food safety and protect public health such as special handling procedures, the Secretary shall exempt pizzas containing a meat food product from the inspection requirements of this chapter if—

(A) the meat food product components of the pizzas have been prepared, inspected, and passed in a cured or cooked form as ready-to-eat in compliance with the requirements of this chapter; and

(B) the pizzas are to be served in public or private nonprofit institutions.

(2) The Secretary may withdraw or modify any exemption under this subsection whenever the Secretary determines such action is necessary to ensure food safety and to protect public health. The Secretary may reinstate or further modify any exemption withdrawn or modified under this subsection.

**(d) Adulteration and misbranding provisions applicable to inspection-free articles**

The adulteration and misbranding provisions of this subchapter, other than the requirement of the inspection legend, shall apply to articles which are exempted from inspection or not required to be inspected under this section.

(Mar. 4, 1907, ch. 2907, title I, § 23, formerly 21st, 22nd pars., 34 Stat. 1265; June 29, 1938, ch. 810, 52 Stat. 1235; renumbered § 23 and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 11, 81 Stat. 584, 591; July 18, 1970, Pub. L. 91–342, 84 Stat. 438; Dec. 13, 1991, Pub. L. 102–237, title X, § 1016(a), 105 Stat. 1902.)

CODIFICATION

Section was formerly classified to sections 91 and 92 of this title.

AMENDMENTS

1991—Subsecs. (c), (d). Pub. L. 102–237 added subsec. (c) and redesignated former subsec. (c) as (d).

1970—Subsec. (a). Pub. L. 91–342 changed proviso so as to permit custom slaughterers to conduct a separate inspected meat business, continued the exemption for owners to slaughter and process their own animals for their own use, authorized the Secretary to exempt custom slaughtering and processing performed by an inspected establishment, and required that custom slaughtered articles be clearly marked ''not for sale''.

1967—Pub. L. 90–201, § 11, substituted provisions for personal, custom, and territorial slaughtering exemptions and for application of adulteration and misbranding provisions to inspection-free articles for farmer definition and retail butcher and retail dealer exemption provisions.

1938—Act June 29, 1948, amended section generally.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective upon expiration of sixty days after Dec. 15, 1967, see section 20(c) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

REGULATIONS

Secretary to issue final rules no later than Aug. 1, 1992, to implement exemption authorized by subsec. (c) of this section, see section 1016(c) of Pub. L. 102–237, set out as a note under section 464 of this title.

**§ 624. Storage and handling regulations; violations; exemption of establishments subject to non-Federal jurisdiction**

The Secretary may by regulations prescribe conditions under which carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, shall be stored or otherwise handled by any person, firm, or corporation engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited. However, such regulations shall not apply to the storage or handling of such articles at any retail store or other establishment in any State or organized Territory that would be subject to this section only because of purchases in commerce, if the storage and handling of such articles at such establishment is regulated under the laws of the State or Territory in which such establishment is located, in a manner which the Secretary, after consultation with the appropriate advisory committee provided for in section 661 of this title, determines is adequate to effectuate the purposes of this section.

(Mar. 4, 1907, ch. 2907, title I, § 24, as added Dec. 15, 1967, Pub. L. 90–201, § 13, 81 Stat. 593.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 623 of this title.

## SUBCHAPTER II—MEAT PROCESSORS AND RELATED INDUSTRIES

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 607, 661, 672, 673 of this title.

**§ 641. Prohibition of subchapter I inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles**

Inspection shall not be provided under subchapter I of this chapter at any establishment for the slaughter of cattle, sheep, swine, goats, horses, mules, or other equines, or the preparation of any carcasses or parts or products of such animals, which are not intended for use as human food, but such articles shall, prior to their offer for sale or transportation in commerce, unless naturally inedible by humans, be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food. No person, firm, or corporation shall buy, sell, transport, or offer for sale or transportation, or receive for transportation, in commerce, or import, any carcasses, parts thereof, meat or meat food products of any such animals, which are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary or are naturally inedible by humans.

(Mar. 4, 1907, ch. 2907, title II, § 201, as added Dec. 15, 1967, Pub. L. 90–201, § 14, 81 Stat. 593.)

EFFECTIVE DATE

Subchapter effective Dec. 15, 1967, see section 20 of Pub. L. 90–201, set out as a note under section 601 of this title.

### § 642. Recordkeeping requirements

#### (a) Classes of persons bound; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples

The following classes of persons, firms, and corporations shall keep such records as will fully and correctly disclose all transactions involved in their businesses; and all persons, firms, and corporations subject to such requirements shall, at all reasonable times upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory upon payment of the fair market value therefor—

(1) Any persons, firms, or corporations that engage, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;

(2) Any persons, firms, or corporations that engage in the business of buying or selling (as meat brokers, wholesalers or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals;

(3) Any persons, firms, or corporations that engage in business, in or for commerce, as renderers, or engage in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

#### (b) Period of maintenance

Any record required to be maintained by this section shall be maintained for such period of time as the Secretary may by regulations prescribe.

(Mar. 4, 1907, ch. 2907, title II, § 202, as added Dec. 15, 1967, Pub. L. 90–201, § 14, 81 Stat. 593.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 645, 661, 678 of this title.

### § 643. Registration of business, name of person, and trade names

No person, firm, or corporation shall engage in business, in or for commerce, as a meat broker, renderer, or animal food manufacturer, or engage in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any cattle, sheep, swine, goats, horses, mules, or other equines, whether intended for human food or other purposes, or engage in business as a public warehouseman storing any such articles in or for commerce, or engage in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased animals of the specified kinds, or parts of the carcasses of any such animals that died otherwise than by slaughter, unless, when required by regulations of the Secretary, he has registered with the Secretary his name, and the address of each place of business at which, and all trade names under which, he conducts such business.

(Mar. 4, 1907, ch. 2907, title II, § 203, as added Dec. 15, 1967, Pub. L. 90–201, § 14, 81 Stat. 594.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 645 of this title.

### § 644. Regulation of transactions, transportation, or importation of 4–D animals to prevent use as human food

No person, firm, or corporation engaged in the business of buying, selling, or transporting in commerce, or importing, dead, dying, disabled, or diseased animals, or any parts of the carcasses of any animals that died otherwise than by slaughter, shall buy, sell, transport, offer for sale or transportation, or receive for transportation, in commerce, or import, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter, unless such transaction, transportation or importation is made in accordance with such regulations as the Secretary may prescribe to assure that such animals, or the unwholesome parts or products thereof, will be prevented from being used for human food purposes.

(Mar. 4, 1907, ch. 2907, title II, § 204, as added Dec. 15, 1967, Pub. L. 90–201, § 14, 81 Stat. 594.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 645 of this title.

### § 645. Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority

The authority conferred on the Secretary by section 642, 643, or 644 of this title with respect to persons, firms, and corporations engaged in the specified kinds of business in or for commerce may be exercised with respect to persons, firms, or corporations engaged, in any State or organized Territory, in such kinds of business but not in or for commerce, whenever the Secretary determines, after consultation with an appropriate advisory committee provided for in section 661 of this title, that the State or territory does not have at least equal authority under its laws or such authority is not exercised in a manner to effectuate the purposes of this chapter including the State providing for the Secretary or his representative being afforded access to such places of business and the facilities, inventories, and records thereof, and the taking of reasonable samples, where he determines necessary in carrying out his responsibilities under this chapter; and in such case the provisions of section 642, 643, or 644 of this title, respectively, shall apply to such persons, firms,

and corporations to the same extent and in the same manner as if they were engaged in such business in or for commerce and the transactions involved were in commerce.

(Mar. 4, 1907, ch. 2907, title II, § 205, as added Dec. 15, 1967, Pub. L. 90–201, § 14, 81 Stat. 594.)

SUBCHAPTER III—FEDERAL AND STATE COOPERATION

**§ 661. Federal and State cooperation**

**(a) Congressional statement of policy**

It is the policy of the Congress to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist in efforts by State and other Government agencies to accomplish this objective. In furtherance of this policy—

**(1) Development and administration of State meat inspection program equal to subchapter I ante and post mortem inspection, reinspection, and sanitation requirements**

The Secretary is authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with the appropriate State agency in developing and administering a State meat inspection program in any State which has enacted a State meat inspection law that imposes mandatory ante mortem and post mortem inspection, reinspection and sanitation requirements that are at least equal to those under subchapter I of this chapter, with respect to all or certain classes of persons engaged in the State in slaughtering cattle, sheep, swine, goats, or equines, or preparing the carcasses, parts thereof, meat or meat food products, of any such animals for use as human food solely for distribution within such State.

**(2) Development and administration of State program with authorities equal to subchapter II authorities; cooperation with Federal agencies**

The Secretary is further authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with appropriate State agencies in developing and administering State programs under State laws containing authorities at least equal to those provided in subchapter II of this chapter; and to cooperate with other agencies of the United States in carrying out any provisions of this chapter.

**(3) Scope of cooperation: advisory assistance, technical and laboratory assistance and training, and financial and other aid; limitation on amount; equitable allocation of Federal funds; adequacy of State program to obtain Federal cooperation and payments**

Cooperation with State agencies under this section may include furnishing to the appropriate State agency (i) advisory assistance in planning and otherwise developing an adequate State program under the State law; and (ii) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other aid for administration of such a program. The amount to be contributed to any State by the Secretary under this section from Federal funds for any year shall not exceed 50 per centum of the estimated total cost of the cooperative program; and the Federal funds shall be allocated among the States desiring to cooperate on an equitable basis. Such cooperation and payment shall be contingent at all times upon the administration of the State program in a manner which the Secretary, in consultation with the appropriate advisory committee appointed under paragraph (4), deems adequate to effectuate the purposes of this section.

**(4) Advisory committees**

The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with him concerning State and Federal programs with respect to meat inspection and other matters within the scope of this chapter, including evaluating State programs for purposes of this chapter and obtaining better coordination and more uniformity among the State programs and between the Federal and State programs and adequate protection of consumers.

**(b) Single State agency; subordinate governmental unit as part of State agency**

The appropriate State agency with which the Secretary may cooperate under this chapter shall be a single agency in the State which is primarily responsible for the coordination of the State programs having objectives similar to those under this chapter. When the State program includes performance of certain functions by a municipality or other subordinate governmental unit, such unit shall be deemed to be a part of the State agency for purposes of this section.

**(c) State meat inspection requirements**

**(1) Notice to Governor of nondevelopment or nonenforcement; designation of State as subject to subchapters I and IV; delay and revocation of designation; publication in Federal Register; notice of production of adulterated meat or meat food products; designation of State**

If the Secretary has reason to believe, by thirty days prior to the expiration of two years after December 15, 1967, that a State has failed to develop or is not enforcing, with respect to all establishments within its jurisdiction (except those that would be exempted from Federal inspection under subparagraph (2)) at which cattle, sheep, swine, goats, or equines are slaughtered, or their carcasses, or parts or products thereof, are prepared for use as human food, solely for distribution within such State, and the products of such establishments, requirements at least equal to those imposed under subchapter I and IV of this chapter, he shall promptly notify the Governor of the State of this fact. If the Secretary determines, after consultation with the Governor of the State, or representative selected by him, that such require-

ments have not been developed and activated, he shall promptly after the expiration of such two-year period designate such State as one in which the provisions of subchapters I and IV of this chapter shall apply to operations and transactions wholly within such State: *Provided*, That if the Secretary has reason to believe that the State will activate such requirements within one additional year, he may delay such designation for said period, and not designate the State, if he determines at the end of the year that the State then has such requirements in effective operation. The Secretary shall publish any such designation in the Federal Register and, upon the expiration of thirty days after such publication, the provisions of subchapters I and IV shall apply to operations and transactions and to persons, firms, and corporations engaged therein in the State to the same extent and in the same manner as if such operations and transactions were conducted in or for commerce. Thereafter, upon request of the Governor, the Secretary shall revoke such designation if the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under subchapter I and subchapter IV of this chapter: *And provided further*, That, notwithstanding any other provision of this section, if the Secretary determines that any establishment within a State is producing adulterated meat or meat food products for distribution within such State which would clearly endanger the public health he shall notify the Governor of the State and the appropriate Advisory Committee provided by section 661 of this title of such fact for effective action under State or local law. If the State does not take action to prevent such endangering of the public health within a reasonable time after such notice, as determined by the Secretary, in light of the risk to public health, the Secretary may forthwith designate any such establishment as subject to the provisions of subchapters I and IV of this chapter, and thereupon the establishment and operator thereof shall be subject to such provisions as though engaged in commerce until such time as the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under subchapter I and subchapter IV of this chapter.

**(2) Exemptions of retail stores, restaurants, and similar retail-type establishments; operations conducted at a restaurant central kitchen facility**

The provisions of this chapter requiring inspection of the slaughter of animals and the preparation of carcasses, parts thereof, meat and meat food products shall not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments if such establishments are subject to such inspection provisions only under this paragraph (c). For the purposes of this subparagraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that are ready to eat when they leave such facility and are served in meals or as entrees only to customers at restaurants owned or operated by the same person, firm, or corporation owning or operating such facility: *Provided*, That such facility shall be subject to the provisions of section 642 of this title: *Provided further*, That the facility may be subject to the inspection requirements under subchapter I of this chapter for as long as the Secretary deems necessary, if the Secretary determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated.

**(3) Termination of designation of State upon development and enforcement of minimum requirements; redesignation; designation for nonenforcement of minimum requirements: notice and publication in Federal Register**

Whenever the Secretary determines that any State designated under this paragraph (c) has developed and will enforce State meat inspection requirements at least equal to those imposed under subchapters I and IV of this chapter with respect to the operations and transactions within such State which are regulated under paragraph (1), he shall terminate the designation of such State under this paragraph (c), but this shall not preclude the subsequent redesignation of the State at any time upon thirty days notice to the Governor and publication in the Federal Register in accordance with this paragraph, and any State may be designated upon such notice and publication at any time after the period specified in this paragraph whether or not the State has theretofore been designated upon the Secretary determining that it is not effectively enforcing requirements at least equal to those imposed under subchapters I and IV of this chapter.

**(4) Periodic review; report to Congressional committees**

The Secretary shall promptly upon December 15, 1967, and periodically thereafter, but at least annually, review the requirements, including the enforcement thereof, of the several States not designated under this paragraph (c), with respect to the slaughter, and the preparation, storage, handling and distribution of carcasses, parts thereof, meat and meat food products, of such animals, and inspection of such operations and annually report thereon to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate in the report required under section 691 of this title.

**(d) "State" defined**

As used in this section, the term ''State'' means any State (including the Commonwealth of Puerto Rico) or organized Territory.

(Mar. 4, 1907, ch. 2907, title III § 301, as added Dec. 15, 1967, Pub. L. 90–201, § 15, 81 Stat. 595; amended Oct. 17, 1984, Pub. L. 98–487, § 1, 98 Stat. 2264; Nov. 2, 1994, Pub. L. 103–437, § 8(2), 108 Stat. 4588.)

CODIFICATION

In subsec. (c)(1), (4), ''December 15, 1967'' substituted for ''enactment of the Wholesome Meat Act''.

AMENDMENTS

1994—Subsec. (c)(4). Pub. L. 103–437 substituted ''Agriculture, Nutrition, and Forestry'' for ''Agriculture and Forestry''.

1984—Subsec. (c)(2). Pub. L. 98–487 inserted provisions relating to operations conducted at a restaurant central kitchen facility.

EFFECTIVE DATE

Section effective Dec. 15, 1967, see section 20 of Pub. L. 90–201, set out as a note under section 601 of this title.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 607, 624, 645 of this title.

## SUBCHAPTER IV—AUXILIARY PROVISIONS

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 661 of this title.

### § 671. Inspection services; refusal or withdrawal; hearing; business unfitness based upon certain convictions; other provisions for withdrawal of services unaffected; responsible connection with business; finality of Secretary's actions; judicial review; record

The Secretary may (for such period, or indefinitely, as he deems necessary to effectuate the purposes of this chapter) refuse to provide, or withdraw, inspection service under subchapter I of this chapter with respect to any establishment if he determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection under subchapter I because the applicant or recipient, or anyone responsibly connected with the applicant or recipient, has been convicted, in any Federal or State court, of (1) any felony, or (2) more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food. This section shall not affect in any way other provisions of this chapter for withdrawal of inspection services under subchapter I from establishments failing to maintain sanitary conditions or to destroy condemned carcasses, parts, meat or meat food products.

For the purpose of this section a person shall be deemed to be responsibly connected with the business if he was a partner, officer, director, holder, or owner of 10 per centum or more of its voting stock or employee in a managerial or executive capacity.

The determination and order of the Secretary with respect thereto under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within thirty days after the effective date of such order in the appropriate court as provided in section 674 of this title. Judicial review of any such order shall be upon the record upon which the determination and order are based.

(Mar. 4, 1907, ch. 2907, title IV, § 401, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 597; amended Nov. 10, 1986, Pub. L. 99–641, title IV, § 403(b), 100 Stat. 3568.)

AMENDMENTS

1986—Subsec. (a). Pub. L. 99–641, § 403(b)(1), (2)(B), (C), temporarily designated provisions which related to authority to refuse or withdraw inspection service as subsec. (a), struck out ''any felony, or (2)'' after ''of (1)'', and inserted ''or (2) any felony'' after ''transactions in food''. See Effective and Termination Dates of 1986 Amendment note below.

Pub. L. 99–641, § 403(b)(2)(A), which directed that subsec. (a) be amended by substituting ''applicant for'' for ''applicant, for'', could not be executed because ''applicant, for'' does not appear.

Subsecs. (b) to (e). Pub. L. 99–641, § 403(b)(6), temporarily added subsecs. (b) to (e). See Effective and Termination Dates of 1986 Amendment note below.

Subsec. (f). Pub. L. 99–641, § 403(b)(3), temporarily designated provisions which related to other provisions for withdrawal of inspection services as subsec. (f). See Effective and Termination Dates of 1986 Amendment note below.

Subsec. (g). Pub. L. 99–641, § 403(b)(4), temporarily designated provisions which related to responsible connection with business as subsec. (g). See Effective and Termination Dates of 1986 Amendment note below.

Subsec. (h). Pub. L. 99–641, § 403(b)(5), temporarily designated provisions which related to finality of determination by Secretary and to judicial review as subsec. (h), substituted ''Except as provided in subsection (e)(2) of this section, the determination'' for ''The determination'' and ''subsection (e) of this section'' for ''this section''. See Effective and Termination Dates of 1986 Amendment note below.

EFFECTIVE AND TERMINATION DATES OF 1986 AMENDMENT

Section 403(b) of Pub. L. 99–641 provided that the amendment made by that section is effective only during the 6-year period beginning Nov. 10, 1986.

EFFECTIVE DATE

Subchapter effective Dec. 15, 1967, see section 20 of Pub. L. 90–201, set out as a note under section 601 of this title.

CONSTRUCTION AND EFFECT OF AMENDMENTS BY PUB. L. 99–641

For provisions relating to construction and effect of temporary amendments by section 403 of Pub. L. 99–641, see sections 403(e) and 404 of Pub. L. 99–641, set out as notes entitled ''Inspection Services for Establishments Not Participating in Total Plant Quality-Control Program'' and ''Savings Provision'', respectively, under section 606 of this title.

### § 672. Administrative detention; duration; pending judicial proceedings; notification of governmental authorities; release

Whenever any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines, or any

product exempted from the definition of a meat food product, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to subchapter I or II of this chapter, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of subchapter I of this chapter or of any other Federal law or the laws of any State or Territory, or the District of Columbia, or that such article or animal has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under section 673 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or animal, and shall not be moved by any person, firm, or corporation from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or animal before it is released unless it appears to the satisfaction of the Secretary that the article or animal is eligible to retain such marks.

(Mar. 4, 1907, ch. 2907, title IV, § 402, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 598.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 159, 679 of this title.

### § 673. Seizure and condemnation

**(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bond; court costs and fees, storage, and other expenses against claimants; proceedings in admiralty; jury trial; United States as plaintiff**

(1) Any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules or other equines, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine, that is being transported in commerce or otherwise subject to subchapter I or II of this chapter, or is held for sale in the United States after such transportation, and that (A) is or has been prepared, sold, transported, or otherwise distributed or offered or received for distribution in violation of this chapter, or (B) is capable of use as human food and is adulterated or misbranded, or (C) in any other way is in violation of this chapter, shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court as provided in section 674 of this title within the jurisdiction of which the article or animal is found.

(2) If the article or animal is condemned it shall, after entry of the decree, (A) be distributed in accordance with paragraph (5), or (B) be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the article or animal shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold: *Provided*, That upon the execution and delivery of a good and sufficient bond conditioned that the article or animal shall not be sold or otherwise disposed of contrary to the provisions of this chapter, or the laws of the jurisdiction in which disposal is made, the court may direct that such article or animal be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws.

(3) When a decree of condemnation is entered against the article or animal and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the article or animal.

(4) The proceedings in such libel cases shall conform, as nearly as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(5)(A) An article that is condemned under paragraph (1) may as the court may direct, after entry of the decree, be distributed without charge to nonprofit, private entities or to Federal, State, or local government entities engaged in the distribution of food without charge to individuals, if such article—

(i) has been inspected under this chapter and found to be wholesome and not to be adulterated within the meaning of paragraphs (1) through (7) and (9) of section 601(m) of this title and a determination is made at the time of the entry of the decree that such article is wholesome and not so adulterated; and

(ii) is plainly marked ''Not for Sale'' on such article or its container.

(B) The United States may not be held legally responsible for any article that is distributed under subparagraph (A) to a nonprofit, private entity or to a Federal, State, or local government entity, if such article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of paragraphs (1) through (7) and (9) of section 601(m) of this title and a determination was made at the time of the entry of the decree that such article was wholesome and not so adulterated; and

(ii) was plainly marked ''Not for Sale'' on such article or its container.

(C) The person from whom such article was seized and condemned may not be held legally responsible for such article, if such article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of paragraphs (1) through (7) and (9) of section 601(m) of this title and a determination was made at the time of the entry of the decree that such article was wholesome and not so adulterated; and

(ii) was plainly marked ''Not for Sale'' on such article or its container.

**(b) Condemnation or seizure under other provisions unaffected**

The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

(Mar. 4, 1907, ch. 2907, title IV, § 403, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 598; amended Dec. 7, 1989, Pub. L. 101–205, § 1, 103 Stat. 1829.)

AMENDMENTS

1989—Subsec. (a). Pub. L. 101–205 designated first sentence as par. (1) and redesignated cls. (1) to (3) as cls. (A) to (C), respectively, designated second sentence as par. (2) and inserted ''(A) to be distributed in accordance with paragraph (5), or (B)'' after ''entry of the decree,'', designated third and fourth sentences as pars. (3) and (4), respectively, and added par. (5).

FEDERAL RULES OF CIVIL PROCEDURE

Admiralty and maritime rules of practice (which included libel procedures) were superseded, and civil and admiralty procedures in United States district courts were unified, effective July 1, 1966, see rule 1 and Supplemental Rules for Certain Admiralty and Maritime Claims, Title 28, Appendix, Judiciary and Judicial Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 159, 672 of this title.

## § 674. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations of section 607(e) of this title

The United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other Territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other kinds of cases arising under this chapter, except as provided in section 607(e) of this title.

(Mar. 4, 1907, ch. 2907, title IV, § 404, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 599.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 159, 671, 673, 677 of this title.

## § 675. Assaulting, resisting, or impeding certain persons; murder; protection of such persons

Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account of the performance of his official duties under this chapter shall be fined not more than $5,000 or imprisoned not more than three years, or both. Whoever, in the commission of any such acts, uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than ten years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this chapter shall be punished as provided under sections 1111 and 1114 of title 18.

(Mar. 4, 1907, ch. 2907, title IV, § 405, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 599.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 159 of this title.

## § 676. Violations

**(a) Misdemeanors; felonies: intent to defraud and distribution of adulterated articles; good faith**

Any person, firm, or corporation who violates any provision of this chapter for which no other criminal penalty is provided by this chapter shall upon conviction be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if such violation involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except as defined in section 601(m)(8) of this title), such person, firm, or corporation shall be subject to imprisonment for not more than three years or a fine of not more than $10,000, or both: *Provided*, That no person, firm, or corporation, shall be subject to penalties under this section for receiving for transportation any article or animal in violation of this chapter if such receipt was made in good faith, unless such person, firm, or corporation refuses to furnish on request of a representative of the Secretary the name and address of the person from whom he received such article or animal, and copies of all documents, if any there be, pertaining to the delivery of the article or animal to him.

**(b) Minor violations; written notice of warning of criminal and civil proceedings**

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

(Mar. 4, 1907, ch. 2907, title IV, § 406, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 599; amended Nov. 10, 1986, Pub. L. 99–641, title IV, § 403(c), 100 Stat. 3570.)

AMENDMENTS

1986—Subsec. (b). Pub. L. 99–641, § 403(c)(1), temporarily inserted provisions which related to factors required to be considered by Secretary in determining whether public interest is served by written notice of warning. See Effective and Termination Dates of 1986 Amendment note below.

Subsec. (c). Pub. L. 99–641, § 403(c)(2), temporarily added subsec. (c). See Effective and Termination Dates of 1986 Amendment note below.

EFFECTIVE AND TERMINATION DATES OF 1986 AMENDMENT

Section 403(c) of Pub. L. 99–641 provided that the amendment made by that section is effective only during the 6-year period beginning Nov. 10, 1986.

CONSTRUCTION AND EFFECT OF AMENDMENTS BY PUB. L. 99–641

For provisions relating to construction and effect of temporary amendments by section 403 of Pub. L. 99–641, see sections 403(e) and 404 of Pub. L. 99–641, set out as notes entitled ''Inspection Services for Establishments Not Participating in Total Plant Quality-Control Program'' and ''Savings Provision'', respectively, under section 606 of this title.

FEDERAL RULES OF CIVIL PROCEDURE

Admiralty and maritime rules of practice (which included libel procedures) were superseded, and civil and admiralty procedures in United States district courts were unified, effective July 1, 1966, see rule 1 and Supplemental Rules for Certain Admiralty and Maritime Claims, Title 28, Appendix, Judiciary and Judicial Procedure.

### § 677. Other Federal laws applicable for administration and enforcement of chapter; location of inquiries; jurisdiction of Federal courts

For the efficient administration and enforcement of this chapter, the provisions (including penalties) of sections 46, 48, 49 and 50 of title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49[1] of title 15), and the provisions of section 409(*l*)[1] of title 47; are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person, firm, or corporation with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of title 15 on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 674 of this title.

(Mar. 4, 1907, ch. 2907, title IV, § 407, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 599.)

REFERENCES IN TEXT

The last paragraph of section 49 of title 15, and the provisions of section 409(*l*) of title 47, referred to in text, which related to immunity of witnesses, were repealed by sections 211 and 242, respectively, of Pub. L. 91–452, Oct. 15, 1970, title II, 84 Stat. 929, 930. For provisions relating to immunity of witnesses, see section 6001 et seq. of Title 18, Crimes and Criminal Procedure.

### § 678. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters

Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement[1] or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

(Mar. 4, 1907, ch. 2907, title IV, § 408, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 600.)

### § 679. Application of Federal Food, Drug, and Cosmetic Act

#### (a) Authorities under food, drug, and cosmetic provisions unaffected

Notwithstanding any other provisions of law, including section 902(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392(a)), the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] prior to December 15, 1967.

#### (b) Enforcement proceedings; detainer authority of representatives of Secretary of Health and Human Services

The detainer authority conferred by section 672 of this title shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] with respect to any carcass, part thereof, meat, or meat food product of cattle, sheep, swine, goats, or equines that is outside any premises at which inspection is being maintained under this chapter, and for such purposes the first reference to the Secretary in section 672 of this title shall be deemed to refer to the Secretary of Health and Human Services.

(Mar. 4, 1907, ch. 2907, title IV, § 409, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 600; amended Oct. 17, 1979, Pub. L. 96–88, title V, § 509(b), 93 Stat. 695.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

[1] See References in Text note below.

[1] So in original. Probably should be "requirements".

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act defined, see section 601 of this title.

### § 680. Authorization of appropriations

There are hereby authorized to be appropriated such sums as may be necessary to carry out the provisions of this chapter.

(Mar. 4, 1907, ch. 2907, title IV, § 410, as added Dec. 15, 1967, Pub. L. 90–201, § 16, 81 Stat. 600.)

## SUBCHAPTER V—MISCELLANEOUS PROVISIONS

### § 691. Reports to Congressional committees

The Secretary shall annually report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate with respect to the slaughter of animals subject to this Act, and the preparation, storage, handling and distribution of carcasses, parts thereof, meat and meat food products, of such animals, and inspection of establishments operated in connection therewith, including the operations under and effectiveness of this Act.

(Pub. L. 90–201, § 17, Dec. 15, 1967, 81 Stat. 600; Pub. L. 103–437, § 8(3), Nov. 2, 1994, 108 Stat. 4588.)

REFERENCES IN TEXT

This Act, referred to in text, means Pub. L. 90–201, Dec. 15, 1967, 81 Stat. 584, as amended, known as the Wholesome Meat Act, which enacted sections 601, 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amended sections 603 to 623 of this title, repealed section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacted provisions set out as notes under section 601 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

CODIFICATION

Section was enacted as a part of the Wholesome Meat Act (see References in Text note above) and not as a part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

AMENDMENTS

1994—Pub. L. 103–437 substituted ''Agriculture, Nutrition, and Forestry'' for ''Agriculture and Forestry''.

EFFECTIVE DATE

Section effective Dec. 15, 1967, see section 20 of Pub. L. 90–201, set out as a note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 661 of this title.

### § 692. Inspection extended to reindeer

The provisions of the meat inspection law may be extended to the inspection of reindeer.

(June 30, 1914, ch. 131, 38 Stat. 420.)

REFERENCES IN TEXT

The meat inspection law, referred to in text, is classified generally to this chapter. At the time of enactment, such reference probably meant the Act of Mar. 4, 1907, ch. 2907, 34 Stat. 1260, as amended. That Act (formerly classified to section 71 et seq. of this title), was generally revised by Pub. L. 90–201, Dec. 15, 1967, 81 Stat. 584, and is classified to this chapter. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to section 94 of this title.

### § 693. Inspection of dairy products for export

The act of March 3, 1891, as amended, for the inspection of live cattle and products thereof, shall be deemed to include dairy products intended for exportation to any foreign country, and the Secretary of Agriculture may apply, under rules and regulations to be prescribed by him, the provisions of said act for inspection and certification appropriate for ascertaining the purity and quality of such products, and may cause the same to be so marked, stamped, or labeled as to secure their identity and make known in the markets of foreign countries to which they may be sent from the United States their purity, quality, and grade; and all the provisions of said act relating to live cattle and products thereof for export shall apply to dairy products so inspected and certified.

(May 23, 1908, ch. 192, 35 Stat. 254.)

REFERENCES IN TEXT

Act of March 3, 1891, referred to in text, is act Mar. 3, 1891, ch. 555, 26 Stat. 1089, which was superseded by act Mar. 4, 1907, ch. 2907, 34 Stat. 1260, as amended by act June 29, 1938, ch. 810, 52 Stat. 1235 (formerly classified to section 71 et seq. of this title). Act Mar. 4, 1907, ch. 2907, was generally revised by Pub. L. 90–201, Dec. 15, 1967, 81 Stat. 584, and is classified to this chapter.

CODIFICATION

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to sections 94a and 132 of this title.

### § 694. Authorization of appropriations

Annual appropriations of the sum of $3,000,000 from the general fund of the Treasury are authorized for the expenses of the inspection of cattle, sheep, swine, and goats and the meat and meat food products thereof which enter into interstate or foreign commerce and for all expenses necessary to carry into effect the provisions of this Act relating to meat inspection, including rent and the employment of labor in Washington and elsewhere, for each year, and in addition there is authorized to be appropriated such other sums as may be necessary in the enforcement of the meat inspection laws.

(June 30, 1906, ch. 3913, 34 Stat. 679; June 26, 1934, ch. 756, § 2, 48 Stat. 1225.)

REFERENCES IN TEXT

This Act, referred to in text, is act June 30, 1906, ch. 3913, 34 Stat. 669, which made appropriations for the Department of Agriculture for the fiscal year ending June 30, 1907.

CODIFICATION

Section 2 of act June 26, 1934, which was classified to section 725a of former Title 31, Money and Finance, repealed the permanent appropriation under the title ''Meat inspection, Bureau of Animal Industry (fiscal year) (3–114)'' effective July 1, 1935, provided that such

portions of any Acts as make permanent appropriations to be expended under such account are amended so as to authorize, in lieu thereof, annual appropriations from the general fund of the Treasury in identical terms and in such amounts as now provided by the laws providing such permanent appropriations, and authorized, in addition thereto, the appropriation of ''such other sums as may be necessary in the enforcement of the meat inspection laws.'' In the original, the parenthetical ''(U.S.C., title 21, secs. 71 to 96, inclusive)'' followed the phrase ''meat inspection laws''. The ''meat inspection laws'' are classified generally to this chapter.

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to section 95 of this title.

### § 695. Payment of cost of meat-inspection service; exception

The cost of inspection rendered on and after July 1, 1948, under the requirements of laws relating to Federal inspection of meat and meat food products shall be borne by the United States except the cost of overtime pursuant to section 394 of title 7.

(June 5, 1948, ch. 423, 62 Stat. 344.)

CODIFICATION

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to section 98 of this title.

## CHAPTER 13—DRUG ABUSE PREVENTION AND CONTROL

SUBCHAPTER I—CONTROL AND ENFORCEMENT

PART A—INTRODUCTORY PROVISIONS

Sec.
801. Congressional findings and declarations: controlled substances.
801a. Congressional findings and declarations: psychotropic substances.
802. Definitions.
803. Repealed.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

811. Authority and criteria for classification of substances.
(a) Rules and regulations of Attorney General; hearing.
(b) Evaluation of drugs and other substances.
(c) Factors determinative of control or removal from schedules.
(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances.
(e) Immediate precursors.
(f) Abuse potential.
(g) Exclusion of non-narcotic substances sold over the counter without a prescription; dextromethorphan; exemption of substances lacking abuse potential.
(h) Temporary scheduling to avoid imminent hazards to public safety.
812. Schedules of controlled substances.
(a) Establishment.
(b) Placement on schedules; findings required.
(c) Initial schedules of controlled substances.
813. Treatment of controlled substance analogues.
814. Removal of exemption of certain drugs.
(a) Removal of exemption.
(b) Factors to be considered.
(c) Specificity of designation.
(d) Reinstatement of exemption with respect to particular drug products.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

821. Rules and regulations.
822. Persons required to register.
(a) Period of registration.
(b) Authorized activities.
(c) Exceptions.
(d) Waiver.
(e) Separate registration.
(f) Inspection.
823. Registration requirements.
(a) Manufacturers of controlled substances in schedule I or II.
(b) Distributors of controlled substances in schedule I or II.
(c) Limits of authorized activities.
(d) Manufacturers of controlled substances in schedule III, IV, or V.
(e) Distributors of controlled substances in schedule III, IV, or V.
(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances.
(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications.
(h) Applicants for distribution of list I chemicals.
824. Denial, revocation, or suspension of registration.
(a) Grounds.
(b) Limits of revocation or suspension.
(c) Service of show cause order; proceedings.
(d) Suspension of registration in cases of imminent danger.
(e) Suspension and revocation of quotas.
(f) Disposition of controlled substances or list I chemicals.
(g) Seizure or placement under seal of controlled substances or list I chemicals.
825. Labeling and packaging.
(a) Symbol.
(b) Unlawful distribution without identifying symbol.
(c) Warning on label.
(d) Containers to be securely sealed.
826. Production quotas for controlled substances.
(a) Establishment of total annual needs.
(b) Individual production quotas; revised quotas.
(c) Manufacturing quotas for registered manufacturers.
(d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years.
(e) Quota increases.
(f) Incidental production exception.
827. Records and reports of registrants.
(a) Inventory.
(b) Availability of records.
(c) Nonapplicability.
(d) Periodic reports to Attorney General.

Sec.
(e) Reporting and recordkeeping requirements of drug conventions.
(f) Investigational uses of drugs; procedures.
(g) Change of address.
828. Order forms.
(a) Unlawful distribution of controlled substances.
(b) Nonapplicability of provisions.
(c) Preservation and availability.
(d) Issuance.
(e) Unlawful acts.
829. Prescriptions.
(a) Schedule II substances.
(b) Schedule III and IV substances.
(c) Schedule V substances.
(d) Non-prescription drugs with abuse potential.
830. Regulation of listed chemicals and certain machines.
(a) Record of regulated transactions.
(b) Reports to Attorney General.
(c) Confidentiality of information obtained by Attorney General; nondisclosure; exceptions.

PART D—OFFENSES AND PENALTIES

841. Prohibited acts A.
(a) Unlawful acts.
(b) Penalties.
(c) Repealed.
(d) Offenses involving listed chemicals.
(e) Boobytraps on Federal property; penalties; ''boobytrap'' defined.
(f) Ten-year injunction as additional penalty.
(g) Wrongful distribution or possession of listed chemicals.
842. Prohibited acts B.
(a) Unlawful acts.
(b) Manufacture.
(c) Penalties.
843. Prohibited acts C.
(a) Unlawful acts.
(b) Communication facility.
(c) Advertisement.
(d) Penalties.
(e) Additional penalties.
844. Penalties for simple possession.
(a) Unlawful acts; penalties.
(b) Repealed.
(c) ''Drug or narcotic offense'' defined.
844a. Civil penalty for possession of small amounts of certain controlled substances.
(a) In general.
(b) Income and net assets.
(c) Prior conviction.
(d) Limitation on number of assessments.
(e) Assessment.
(f) Compromise.
(g) Judicial review.
(h) Civil action.
(i) Limitation.
(j) Expungement procedures.
845 to 845b. Transferred.
846. Attempt and conspiracy.
847. Additional penalties.
848. Continuing criminal enterprise.
(a) Penalties; forfeitures.
(b) Life imprisonment for engaging in continuing criminal enterprise.
(c) ''Continuing criminal enterprise'' defined.
(d) Suspension of sentence and probation prohibited.
(e) Death penalty.
(g) Hearing required with respect to death penalty.
(h) Notice by Government in death penalty cases.
Sec.
(i) Hearing before court or jury.
(j) Proof of aggravating and mitigating factors.
(k) Return of findings.
(*l*) Imposition of sentence.
(m) Mitigating factors.
(n) Aggravating factors for homicide.
(*o*) Right of defendant to justice without discrimination.
(p) Sentencing in capital cases in which death penalty is not sought or imposed.
(q) Appeal in capital cases; counsel for financially unable defendants.
(r) Refusal to participate by State and Federal correctional employees.
849. Transportation safety offenses.
(a) Definitions.
(b) First offense.
(c) Subsequent offense.
850. Information for sentencing.
851. Proceedings to establish prior convictions.
(a) Information filed by United States Attorney.
(b) Affirmation or denial of previous conviction.
(c) Denial; written response; hearing.
(d) Imposition of sentence.
(e) Statute of limitations.
852. Application of treaties and other international agreements.
853. Criminal forfeitures.
(a) Property subject to criminal forfeiture.
(b) Meaning of term ''property''.
(c) Third party transfers.
(d) Rebuttable presumption.
(e) Protective orders.
(f) Warrant of seizure.
(g) Execution.
(h) Disposition of property.
(i) Authority of the Attorney General.
(j) Applicability of civil forfeiture provisions.
(k) Bar on intervention.
(*l*) Jurisdiction to enter orders.
(m) Depositions.
(n) Third party interests.
(*o*) Construction.
(p) Forfeiture of substitute property.
853a. Transferred.
854. Investment of illicit drug profits.
(a) Prohibition.
(b) Penalty.
(c) ''Enterprise'' defined.
(d) Construction.
855. Alternative fine.
856. Establishment of manufacturing operations.
857. Repealed.
858. Endangering human life while illegally manufacturing controlled substance.
859. Distribution to persons under age twenty-one.
(a) First offense.
(b) Second offense.
860. Distribution or manufacturing in or near schools and colleges.
(a) Penalty.
(b) Second offenders.
(c) Employing children to distribute drugs near schools or playgrounds.
(d) Suspension of sentence; probation; parole.
(e) Definitions.
861. Employment or use of persons under 18 years of age in drug operations.
(a) Unlawful acts.
(b) Penalty for first offense.
(c) Penalty for subsequent offenses.
(d) Penalty for providing or distributing controlled substance to underage person.

Sec.
(e) Suspension of sentence; probation; parole.
(f) Distribution of controlled substance to pregnant individual.
862. Denial of Federal benefits to drug traffickers and possessors.
(a) Drug traffickers.
(b) Drug possessors.
(c) Suspension of period of ineligibility.
(d) Definitions.
(e) Inapplicability of this section to Government witnesses.
(f) Indian provision.
(g) Presidential report.
(h) Effective date.
863. Drug paraphernalia.
(a) In general.
(b) Penalties.
(c) Seizure and forfeiture.
(d) ''Drug paraphernalia'' defined.
(e) Matters considered in determination of what constitutes drug paraphernalia.
(f) Exemptions.

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

871. Attorney General.
(a) Delegation of functions.
(b) Rules and regulations.
(c) Acceptance of devises, bequests, gifts, and donations.
872. Education and research programs of Attorney General.
(a) Authorization.
(b) Contracts.
(c) Identification of research populations; authorization to withhold.
(d) Affect of treaties and other international agreements on confidentiality.
(e) Use of controlled substances in research.
(f) Program to curtail diversion of precursor and essential chemicals.
873. Cooperative arrangements.
(a) Cooperation of Attorney General with local, State, and Federal agencies.
(b) Requests by Attorney General for assistance from Federal agencies or instrumentalities.
(c) Descriptive and analytic reports by Attorney General to State agencies of distribution patterns of schedule II substances having highest rates of abuse.
(d) Grants by Attorney General.
874. Advisory committees.
875. Administrative hearings.
(a) Power of Attorney General.
(b) Procedures applicable.
876. Subpenas.
(a) Authorization of use by Attorney General.
(b) Service.
(c) Enforcement.
877. Judicial review.
878. Powers of enforcement personnel.
879. Search warrants.
880. Administrative inspections and warrants.
(a) ''Controlled premises'' defined.
(b) Grant of authority; scope of inspections.
(c) Situations not requiring warrants.
(d) Administrative inspection warrants; issuance; execution; probable cause.
881. Forfeitures.
(a) Subject property.
(b) Seizure pursuant to Supplemental Rules for Certain Admiralty and Maritime Claims issuance of warrant authorizing seizure.
(c) Custody of Attorney General.
(d) Other laws and proceedings applicable.
(e) Disposition of forfeited property.
(f) Forfeiture and destruction of schedule I and II substances.
(g) Plants.
(h) Vesting of title in United States.
(i) Stay of civil forfeiture proceedings.
(j) Venue.
(*l*) Agreement between Attorney General and Postal Service for performance of functions.
881–1, 881a. Transferred.
882. Injunctions.
(a) Jurisdiction.
(b) Jury trial.
883. Enforcement proceedings.
884. Immunity and privilege.
(a) Refusal to testify.
(b) Order of United States district court.
(c) Request by United States attorney.
885. Burden of proof; liabilities.
(a) Exemptions and exceptions; presumption in simple possession offenses.
(b) Registration and order forms.
(c) Use of vehicles, vessels, and aircraft.
(d) Immunity of Federal, State, local and other officials.
886. Payments and advances.
(a) Payment to informers.
(b) Reimbursement for purchase of controlled substances.
(c) Advance of funds for enforcement purposes.
(d) Drug Pollution Fund.
886a. Diversion Control Fee Account.
887. Coordination and consolidation of post-seizure administration.
888. Expedited procedures for seized conveyances.
(a) Petition for expedited decision; determination.
(b) Written notice of procedures.
(c) Complaint for forfeiture.
(d) Bond for release of conveyance.
889. Production control of controlled substances.
(a) Definitions.
(b) Persons ineligible for Federal agricultural program benefits.
(c) Regulations.

PART F—GENERAL PROVISIONS

901. Severability.
902. Savings provisions.
903. Application of State law.
904. Payment of tort claims.

SUBCHAPTER II—IMPORT AND EXPORT

951. Definitions.
952. Importation of controlled substances.
(a) Controlled substances in schedule I or II and narcotic drugs in schedule III, IV, or V; exceptions.
(b) Nonnarcotic controlled substances in schedule III, IV, or V.
(c) Coca leaves.
953. Exportation of controlled substances.
(a) Narcotic drugs in schedule I, II, III, or IV.
(b) Exception for exportation for special scientific purposes.
(c) Nonnarcotic controlled substances in schedule I or II.
(d) Exception for exportation for special scientific purposes.
(e) Nonnarcotic controlled substances in schedule III or IV; controlled substances in schedule V.
954. Transshipment and in-transit shipment of controlled substances.

Sec.
955. Possession on board vessels, etc., arriving in or departing from United States.
955a to 955d. Transferred.
956. Exemption authority.
(a) Individual possessing controlled substance.
(b) Compound, mixture, or preparation.
957. Persons required to register.
(a) Coverage.
(b) Exemptions.
958. Registration requirements.
(a) Applicants to import or export controlled substances in schedule I or II.
(b) Activity limited to specified substances.
(c) Applicants to import controlled substances in schedule III, IV, or V or to export controlled substances in schedule III or IV; applicants to import or export list I chemicals.
(d) Denial of applications.
(e) Registration period.
(f) Rules and regulations.
(g) Scope of authorized activity.
(h) Separate registrations for each principal place of business.
(i) Emergency situations.
959. Possession, manufacture, or distribution of controlled substance.
(a) Manufacture or distribution for purpose of unlawful importation.
(b) Possession, manufacture, or distribution by person on board aircraft.
(c) Acts committed outside territorial jurisdiction of United States; venue.
960. Prohibited acts A.
(a) Unlawful acts.
(b) Penalties.
(c) Repealed.
(d) Penalty for importation or exportation.
961. Prohibited acts B.
962. Second or subsequent offenses.
(a) Term of imprisonment and fine.
(b) Determination of status.
(c) Procedures applicable.
963. Attempt and conspiracy.
964. Additional penalties.
965. Applicability of part E of subchapter I.
966. Authority of Secretary of the Treasury.
967. Smuggling of controlled substances; investigations; oaths; subpenas; witnesses; evidence; production of records; territorial limits; fees and mileage of witnesses.
968. Service of subpena; proof of service.
969. Contempt proceedings.
970. Criminal forfeitures.
971. Notification, suspension of shipment, and penalties with respect to importation and exportation of listed chemicals.
(a) Notification prior to transaction.
(b) Regular customers or importers.
(c) Suspension of importation or exportation; disqualification of regular customers or importers; hearing.
(d) Broker or trader for international transaction in listed chemical.
(e) Application of notification requirement to exports of listed chemical; waiver.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 801a of this title; title 10 section 374; title 18 section 3582; title 19 section 1595a; title 22 sections 283s, 284k, 285p; title 28 section 524; title 42 section 2000e–2; title 46 App. section 1903.

## SUBCHAPTER I—CONTROL AND ENFORCEMENT

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 333, 951, 952, 958, 960, 965, 971 of this title; title 12 section 3420; title 15 section 5110; title 16 section 559d; title 18 sections 924, 929, 981, 986, 1864, 1956, 3142, 3554, 3592; title 22 sections 2708, 2714; title 23 section 159; title 28 section 524; title 29 section 706; title 40 section 304m; title 42 sections 242, 261, 3751, 12111, 12210.

### PART A—INTRODUCTORY PROVISIONS

### § 801. Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

(Pub. L. 91–513, title II, § 101, Oct. 27, 1970, 84 Stat. 1242.)

REFERENCES IN TEXT

This subchapter, referred to in par. (1), was in the original ''this title'', meaning title II of Pub. L. 91–513,

Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out below and Tables.

EFFECTIVE DATE

Section 704 of title II of Pub. L. 91–513 provided that: ''(a) Except as otherwise provided in this section, this title [see Short Title note below] shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment [Oct. 27, 1970].

''(b) Parts A, B, E, and F of this title [Parts A, B, E, and F of this subchapter], section 702 [set out as a note under section 321 of this title], this section, and sections 705 through 709 [sections 901 to 904 of this title and note set out below], shall become effective upon enactment [Oct. 27, 1970].

''(c) Sections 305 (relating to labels and labeling) [section 825 of this title], and 306 (relating to manufacturing quotas) [section 826 of this title] shall become effective on the date specified in subsection (a) of this section, except that the Attorney General may by order published in the Federal Register postpone the effective date of either or both of these sections for such period as he may determine to be necessary for the efficient administration of this title [see Short Title note below].''

SHORT TITLE OF 1994 AMENDMENT

Pub. L. 103–322, title XVIII, §180201(a), Sept. 13, 1994, 108 Stat. 2046, provided that: ''This section [enacting section 849 of this title, amending section 841 of this title, and enacting provisions set out as a note under section 994 of Title 28, Judiciary and Judicial Procedure] may be cited as the 'Drug Free Truck Stop Act'.''

SHORT TITLE OF 1993 AMENDMENT

Pub. L. 103–200, §1, Dec. 17, 1993, 107 Stat. 2333, provided that: ''This Act [enacting section 814 of this title, amending sections 802, 821 to 824, 830, 843, 880, 957, 958, 960, and 971 of this title, and enacting provisions set out as a note under section 802 of this title] may be cited as the 'Domestic Chemical Diversion Control Act of 1993'.''

SHORT TITLE OF 1990 AMENDMENT

Pub. L. 101–647, title XIX, §1901, Nov. 29, 1990, 104 Stat. 4851, provided that: ''This Act [probably means title XIX of Pub. L. 101–647, which amended sections 333, 802, 812, and 844 of this title and section 290aa–6 of Title 42, The Public Health and Welfare, repealed section 333a of this title, and enacted provisions set out as notes under sections 802 and 829 of this title] may be cited as the 'Anabolic Steroids Control Act of 1990'.''

SHORT TITLE OF 1988 AMENDMENT

Pub. L. 100–690, title VI, §6001, Nov. 18, 1988, 102 Stat. 4312, provided that: ''This title [see Tables for classification] may be cited as the 'Anti-Drug Abuse Amendments Act of 1988'.''

Pub. L. 100–690, title VI, §6051, Nov. 18, 1988, 102 Stat. 4312, provided that: ''This subtitle [subtitle A (§§6051–6061) of title VI of Pub. L. 100–690, enacting section 971 of this title, amending sections 802, 830, 841 to 843, 872, 876, 881, 960, and 961 of this title, and enacting provisions set out as notes under sections 802 and 971 of this title] may be cited as the 'Chemical Diversion and Trafficking Act of 1988'.''

Pub. L. 100–690, title VI, §6071, Nov. 18, 1988, 102 Stat. 4320, provided that: ''This subtitle [subtitle B (§§6071–6080) of title VI of Pub. L. 100–690, enacting sections 881–1, 887, and 1509 of this title, amending section 881 of this title, section 1594 of Title 19, Customs Duties, section 524 of Title 28, Judiciary and Judicial Procedure, and section 782 of former Title 49, Transportation, and enacting provisions set out as notes under section 881 of this title] may be cited as the 'Asset Forfeiture Amendments Act of 1988'.''

SHORT TITLE OF 1986 AMENDMENT

Pub. L. 99–570, §1, Oct. 27, 1986, 100 Stat. 3207, provided that: ''This Act [see Tables for classification] may be cited as the 'Anti-Drug Abuse Act of 1986'.''

Pub. L. 99–570, title I, §1001, Oct. 27, 1986, 100 Stat. 3207–2, provided that: ''This subtitle [subtitle A (§§1001–1009) of title I of Pub. L. 99–570, amending sections 802, 841, 845, 845a, 848, 881, 960, and 962 of this title, sections 3553 and 3583 of Title 18, Crimes and Criminal Procedure, rule 35 of the Federal Rules of Criminal Procedure, Title 18, Appendix, and section 994 of Title 28, Judiciary and Judicial Procedure, and enacting provisions set out as notes under section 841 of this title, sections 3553 and 3583 of Title 18, and rule 35 of the Federal Rules of Criminal Procedure] may be cited as the 'Narcotics Penalties and Enforcement Act of 1986'.''

Pub. L. 99–570, title I, §1051, Oct. 27, 1986, 100 Stat. 3207–8, provided that: ''This subtitle [subtitle B (§§1051, 1052) of title I of Pub. L. 99–570, amending section 844 of this title] may be cited as the 'Drug Possession Penalty Act of 1986'.''

Pub. L. 99–570, title I, §1101, Oct. 27, 1986, 100 Stat. 3207–10, provided that: ''This subtitle [subtitle C (§§1101–1105) of title I of Pub. L. 99–570, enacting section 845b of this title and amending sections 841, 845, and 845a of this title] may be cited as the 'Juvenile Drug Trafficking Act of 1986'.''

Pub. L. 99–570, title I, §1201, Oct. 27, 1986, 100 Stat. 3207–13, provided that: ''This subtitle [subtitle E (§§1201–1204) of title I of Pub. L. 99–570, enacting section 813 of this title and amending section 802 of this title] may be cited as the 'Controlled Substance Analogue Enforcement Act of 1986'.''

Pub. L. 99–570, title I, §1251, Oct. 27, 1986, 100 Stat. 3207–14, provided that: ''This subtitle [subtitle F (§§1251–1253) of title I of Pub. L. 99–570, amending section 848 of this title] may be cited as the 'Continuing Drug Enterprises Act of 1986'.''

Pub. L. 99–570, title I, §1301, Oct. 27, 1986, 100 Stat. 3207–15, provided that: ''This subtitle [subtitle G (§§1301, 1302) of title I of Pub. L. 99–570, amending section 960 of this title] may be cited as the 'Controlled Substances Import and Export Penalties Enhancement Act of 1986'.''

Pub. L. 99–570, title I, §1821, Oct. 27, 1986, 100 Stat. 3207–51, which provided that subtitle O (§§1821–1823) of title I of Pub. L. 99–570, enacting section 857 of this title and provisions set out as a note under section 857 of this title, was to be cited as the ''Mail Order Drug Paraphernalia Control Act'', was repealed by Pub. L. 101–647, title XXIV, §2401(d), Nov. 29, 1990, 104 Stat. 4859.

Pub. L. 99–570, title I, §1991, Oct. 27, 1986, 100 Stat. 3207–59, provided that: ''This subtitle [subtitle U (§§1991, 1992) of title I of Pub. L. 99–570, amending section 881 of this title] may be cited as the 'Federal Drug Law Enforcement Agent Protection Act of 1986'.''

SHORT TITLE OF 1984 AMENDMENT

Pub. L. 98–473, title II, §501, Oct. 12, 1984, 98 Stat. 2068, provided that: ''This chapter [chapter V (§§501–525) of title II of Pub. L. 98–473, enacting section 845a of this title, amending sections 802, 811, 812, 822–824, 827, 841, 843, 845, 873, 881, 952, 953, 957, 958, 960, and 962 of this title, and enacting provisions set out as a note under this section] may be cited as the 'Controlled Substances Penalties Amendments Act of 1984'.''

Pub. L. 98–473, title II, §506(a), Oct. 12, 1984, 98 Stat. 2070, provided that: ''This part [part B of chapter V (§§506–525) of title II of Pub. L. 98–473, amending sections 802, 811, 812, 822–824, 827, 843, 873, 881, 952, 953, 957, and 958 of this title] may be cited as the 'Dangerous Drug Diversion Control Act of 1984'.''

SHORT TITLE OF 1978 AMENDMENT

Pub. L. 95–633, §1, Nov. 10, 1978, 92 Stat. 3768, provided: ''That this Act [enacting sections 801a, 830, and 852 of this title, amending sections 352, 802, 811, 812, 823, 827, 841 to 843, 872, 881, 952, 953, and 965 of this title and section 242a of Title 42, The Public Health and Welfare, re-

pealing section 830 of this title (effective Jan. 1, 1981), and enacting provisions set out as notes under sections 801a, 812, and 830 of this title] may be cited as the 'Psychotropic Substances Act of 1978'.''

SHORT TITLE OF 1974 AMENDMENT

Pub. L. 93–281, § 1, May 14, 1974, 88 Stat. 124, provided: ''That this Act [amending sections 802, 823, 824, and 827 of this title] may be cited as the 'Narcotic Addict Treatment Act of 1974'.''

SHORT TITLE

Pub. L. 91–513, in the provisions preceding section 1 immediately following the enacting clause, provided: ''That this Act [enacting this chapter and sections 257a, 2688*l*–1, 2688n–1, and 3509 of Title 42, The Public Health and Welfare, amending sections 162, 198a, 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114, 1952, and 4251 of Title 18, Crimes and Criminal Procedure, sections 1584, 2078, 2079, and 2080 of Title 19, Customs Duties, sections 4901, 4905, 6808, 7012, 7103, 7326, 7607, 7609, 7641, 7651, and 7655 of Title 26, Internal Revenue Code, section 2901 of Title 28, Judiciary and Judicial Procedure, section 304m of Title 40, Public Buildings, Property, and Works, sections 201, 225a, 242, 242a, 246, 257, 258, 259, 260, 261, 261a, 2688k, 2688*l*, 2688m, 2688n, 2688*o*, 2688r, and 3411 of Title 42, The Public Health and Welfare, section 239a of former Title 46, Shipping, and section 787 of Title 49, Appendix, Transportation, repealing sections 171 to 174, 176 to 185, 188 to 188n, 191 to 193, 197, 198, 199, 360a, and 501 to 517 of this title, sections 1401 to 1407 and 3616 of Title 18, sections 4701 to 4707, 4711 to 4716, 4721 to 4726, 4731 to 4736, 4741 to 4746, 4751 to 4757, 4761, 4762, 4771 to 4776, 7237, 7238, and 7491 of Title 26, sections 529a and 529g of former Title 31, Money and Finance, and section 1421m of Title 48, Territories and Insular Possessions, and enacting provisions set out as notes under this section and sections 171, 321, 822, 951, and 957 of this title] may be cited as the 'Comprehensive Drug Abuse Prevention and Control Act of 1970'.''

Section 100 of title II of Pub. L. 91–513 provided that: ''This title [enacting this subchapter, repealing section 360a of this title, amending sections 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114 and 1952 of Title 18, Crimes and Criminal Procedure, and section 242 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under this section and sections 321 and 822 of this title] may be cited as the 'Controlled Substances Act'.''

CONTINUATION OF ORDERS, RULES, AND REGULATIONS

Section 705 of title II of Pub. L. 91–513 provided that: ''Any orders, rules, and regulations which have been promulgated under any law affected by this title [see Short Title note above] and which are in effect on the day preceding enactment of this title [Oct. 27, 1970] shall continue in effect until modified, superseded, or repealed.''

JOINT FEDERAL TASK FORCE ON ILLEGAL DRUG LABORATORIES

Pub. L. 100–690, title II, § 2405, Nov. 18, 1988, 102 Stat. 4231, provided that:

''(a) ESTABLISHMENT OF TASK FORCE.—There is established the Joint Federal Task Force on Illegal Drug Laboratories (hereafter in this section referred to as the 'Task Force').

''(b) APPOINTMENT AND MEMBERSHIP OF TASK FORCE.—The members of the Task Force shall be appointed by the Administrators of the Environmental Protection Agency and the Drug Enforcement Administration (hereafter in this section referred to as the 'Administrators'). The Task Force shall consist of at least 6 and not more than 20 members. Each Administrator shall appoint one-half of the members as follows: (1) the Administrator of the Environmental Protection Agency shall appoint members from among Emergency Response Technicians and other appropriate employees of the Agency; and (2) the Administrator of the Drug Enforcement Administration shall appoint members from among Special Agents assigned to field divisions and other appropriate employees of the Administration.

''(c) DUTIES OF TASK FORCE.—The Task Force shall formulate, establish, and implement a program for the cleanup and disposal of hazardous waste produced by illegal drug laboratories. In formulating such program, the Task Force shall consider the following factors:

''(1) The volume of hazardous waste produced by illegal drug laboratories.

''(2) The cost of cleaning up and disposing of hazardous waste produced by illegal drug laboratories.

''(3) The effectiveness of the various methods of cleaning up and disposing of hazardous waste produced by illegal drug laboratories.

''(4) The coordination of the efforts of the Environmental Protection Agency and the Drug Enforcement Administration in cleaning up and disposing of hazardous waste produced by illegal drug laboratories.

''(5) The dissemination of information to law enforcement agencies that have responsibility for enforcement of drug laws.

''(d) GUIDELINES.—The Task Force shall recommend to the Administrators guidelines for cleanup of illegal drug laboratories to protect the public health and environment. Not later than 180 days after the date of the enactment of this subtitle [Nov. 18, 1988], the Administrators shall formulate and publish such guidelines.

''(e) DEMONSTRATION PROJECTS.—

''(1) The Attorney General shall make grants to, and enter into contracts with, State and local governments for demonstration projects to clean up and safely dispose of substances associated with illegal drug laboratories which may present a danger to public health or the environment.

''(2) The Attorney General may not under this subsection make a grant or enter into a contract unless the applicant for such assistance agrees to comply with the guidelines issued pursuant to subsection (d).

''(3) The Attorney General shall, through grant or contract, provide for independent evaluations of the activities carried out pursuant to this subsection and shall recommend appropriate legislation to the Congress.

''(f) FUNDING.—Of the amounts made available to carry out the Controlled Substances Act [21 U.S.C. 801 et seq.] for fiscal year 1989, not less than $5,000,000 shall be made available to carry out subsections (d) and (e).

''(g) REPORTS.—After consultation with the Task Force, the Administrators shall—

''(1) transmit to the President and to each House of Congress not later than 270 days after the date of the enactment of this subtitle [Nov. 18, 1988] a report describing the program established by the Task Force under subsection (c) (including an analysis of the factors specified in paragraphs (1) through (5) of that subsection);

''(2) periodically transmit to the President and to each House of Congress reports describing the implementation of the program established by the Task Force under subsection (c) (including an analysis of the factors specified in paragraphs (1) through (5) of that subsection) and the progress made in the cleanup and disposal of hazardous waste produced by illegal drug laboratories; and

''(3) transmit to each House of Congress a report describing the findings made as a result of the evaluations referred to in subsection (e)(3).''

GREAT LAKES DRUG INTERDICTION

Pub. L. 100–690, title VII, § 7404, Nov. 18, 1988, 102 Stat. 4484, provided that:

''(a) INTERAGENCY AGREEMENT.—The Secretary of Transportation and the Secretary of the Treasury shall enter into an agreement for the purpose of increasing the effectiveness of maritime drug interdiction activities of the Coast Guard and the Customs Service in the Great Lakes area.

''(b) NEGOTIATIONS WITH CANADA ON DRUG ENFORCEMENT COOPERATION.—The Secretary of State is encour-

aged to enter into negotiations with appropriate officials of the Government of Canada for the purpose of establishing an agreement between the United States and Canada which provides for increased cooperation and sharing of information between United States and Canadian law enforcement officials with respect to law enforcement efforts conducted on the Great Lakes between the United States and Canada.''

GAO STUDY OF CAPABILITIES OF UNITED STATES TO CONTROL DRUG SMUGGLING INTO UNITED STATES

Pub. L. 100–180, div. A, title XII, §1241, Dec. 4, 1987, 101 Stat. 1162, directed Comptroller General of the United States to conduct a comprehensive study regarding smuggling of illegal drugs into United States and current capabilities of United States to deter such smuggling, with special consideration given to issues involving use of military and National Guard units along with Customs Service in cooperative drug smuggling interdiction efforts, and to issue, not later than Apr. 30, 1988, and Mar. 31, 1989, reports to Congress outlining results of this study.

COMPLIANCE WITH BUDGET ACT

Pub. L. 99–570, §3, Oct. 27, 1986, 100 Stat. 3207–1, provided that: ''Notwithstanding any other provision of this Act [see Tables for classification], any spending authority and any credit authority provided under this Act shall be effective for any fiscal year only to such extent or in such amounts as are provided in appropriation Acts. For purposes of this Act, the term 'spending authority' has the meaning provided in section 401(c)(2) of the Congressional Budget Act of 1974 [2 U.S.C. 651(c)(2)] and the term 'credit authority' has the meaning provided in section 3(10) of the Congresssional [sic] Budget Act of 1974 [2 U.S.C. 622(10)].''

DRUG INTERDICTION

Pub. L. 99–570, title III, §§3001–3003, 3301, Oct. 27, 1986, 100 Stat. 3207–73, 3207–74, 3207–98, provided that:

''SEC. 3001. SHORT TITLE.

''This title [enacting section 379 of Title 10, Armed Forces, sections 1590, 1628, 1629, and 2081 of Title 19, Customs Duties, and section 312a of Title 47, Telegraphs, Telephones, and Radiotelegraphs, amending section 959 of this title, sections 374 and 911 of Title 10, sections 507, 1401, 1433, 1436, 1454, 1459, 1497, 1509, 1584 to 1586, 1594 to 1595a, 1613, 1613b, 1619, and 1622 of Title 19, section 5316 of Title 31, Money and Finance, section 12109 of Title 46, Shipping, sections 1901 to 1904 of Title 46, Appendix, Shipping, and sections 1401, 1472, 1474, and 1509 of former Title 49, Transportation, repealing section 1460 of Title 19, enacting provisions set out as notes under section 801 of this title, sections 371, 374, 525, and 9441 of Title 10, sections 1613b and 1654 of Title 19, section 403 of Title 23, Highways, section 1901 of Title 46, Appendix, section 11344 of Title 49, and section 1509 of former Title 49, and repealing provisions set out as a note under section 89 of Title 14, Coast Guard] may be cited as the 'National Drug Interdiction Improvement Act of 1986'.

''SEC. 3002. FINDINGS.

''The Congress hereby finds that—

''(1) a balanced, coordinated, multifaceted strategy for combating the growing drug abuse and drug trafficking problem in the United States is essential in order to stop the flow and abuse of drugs within our borders;

''(2) a balanced, coordinated, multifaceted strategy for combating the narcotics drug abuse and trafficking in the United States should include—

''(A) increased investigations of large networks of drug smuggler organizations;

''(B) source country drug eradication;

''(C) increased emphasis on stopping narcotics traffickers in countries through which drugs are transshipped;

''(D) increased emphasis on drug education programs in the schools and workplace;

''(E) increased Federal Government assistance to State and local agencies, civic groups, school systems, and officials in their efforts to combat the drug abuse and trafficking problem at the local level; and

''(F) increased emphasis on the interdiction of drugs and drug smugglers at the borders of the United States, in the air, at sea, and on the land;

''(3) funds to support the interdiction of narcotics smugglers who threaten the transport of drugs through the air, on the sea, and across the land borders of the United States should be emphasized in the Federal Government budget process to the same extent as the other elements of a comprehensive anti-drug effort are emphasized;

''(4) the Department of Defense and the use of its resources should be an integral part of a comprehensive, natonal [national] drug interdiction program;

''(5) the Federal Government civilian agencies engaged in drug interdiction, particularly the United States Customs Service and the Coast Guard, currently lack the aircraft, ships, radar, command, control, communications, and intelligence (C3I) system, and manpower resources necessary to mount a comprehensive attack on the narcotics traffickers who threaten the United States;

''(6) the civilian drug interdiction agencies of the United States are currently interdicting only a small percentage of the illegal, drug smuggler penetrations in the United States every year;

''(7) the budgets for our civilian drug interdiction agencies, primarily the United States Customs Service and the Coast Guard, have not kept pace with those of the traditional investigative law enforcement agencies of the Department of Justice; and

''(8) since the amendment of the Posse Comitatus Act (18 U.S.C. 1385) in 1981, the Department of Defense has assisted in the effort to interdict drugs, but they can do more.

''SEC. 3003. PURPOSES.

''It is the purpose of this title—

''(1) to increase the level of funding and resources available to civilian drug interdiction agencies of the Federal Government;

''(2) to increase the level of support from the Department of Defense as consistent with the Posse Comitatus Act [18 U.S.C. 1385], for interdiction of the narcotics traffickers before such traffickers penetrate the borders of the United States; and

''(3) to improve other drug interdiction programs of the Federal Government.

''SEC. 3301. ESTABLISHMENT OF A UNITED STATES-BAHAMAS DRUG INTERDICTION TASK FORCE

''(a) AUTHORIZATION OF APPROPRIATIONS.—

''(1) ESTABLISHMENT OF A UNITED STATES-BAHAMAS DRUG INTERDICTION TASK FORCE.—(A) There is authorized to be established a United States-Bahamas Drug Interdiction Task Force to be operated jointly by the United States Government and the Government of the Bahamas.

''(B) The Secretary of State, the Commandant of the Coast Guard, the Commissioner of Customs, the Attorney General, and the head of the National Narcotics Border Interdiction System (NNBIS), shall upon enactment of this Act [Oct. 27, 1986], immediately commence negotiations with the Government of the Bahamas to enter into a detailed agreement for the establishment and operation of a new drug interdiction task force, including plans for (i) the joint operation and maintenance of any drug interdiction assets authorized for the task force in this section and section 3141 [see 19 U.S.C. 2075], and (ii) any training and personnel enhancements authorized in this section and section 3141.

''(C) The Attorney General shall report to the appropriate committees of Congress on a quarterly basis regarding the progress of the United States-Bahamas Drug Interdiction Task Force.

''(2) AMOUNTS AUTHORIZED.—There are authorized to be appropriated, in addition to any other amounts au-

thorized to be appropriated in this title [see section 3001 of Pub. L. 99–570 set out above], $10,000,000 for the following:

''(A) $9,000,000 for 3 drug interdiction pursuit helicopters for use primarily for operations of the United States-Bahamas Drug Interdiction Task Force established under this section; and

''(B) $1,000,000 to enhance communications capabilities for the operation of a United States-Bahamas Drug Interdiction Task Force established under this section.

''(3) COAST GUARD-BAHAMAS DRUG INTERDICTION DOCKING FACILITY.—(A) There is authorized to be appropriated for acquisition, construction, and improvements for the Coast Guard for fiscal year 1987, $5,000,000, to be used for initial design engineering, and other activities for construction of a drug interdiction docking facility in the Bahamas to facilitate Coast Guard and Bahamian drug interdiction operations in and through the Bahama Islands. Of the amounts authorized to be appropriated in this subsection, such sums as may be necessary shall be available for necessary communication and air support.

''(B) The Commandant of the Coast Guard shall use such amounts appropriated pursuant to the authorization in this paragraph as may be necessary to establish a repair, maintenance, and boat lift facility to provide repair and maintenance services for both Coast Guard and Bahamian marine drug interdiction equipment, vessels, and related assets.

''(b) CONCURRENCE BY SECRETARY OF STATE.—Programs authorized by this section may be carried out only with the concurrence of the Secretary of State.''

INFORMATION ON DRUG ABUSE AT THE WORKPLACE

Pub. L. 99–570, title IV, § 4303, Oct. 27, 1986, 100 Stat. 3207–154, directed Secretary of Labor to collect such information as is available on the incidence of drug abuse in the workplace and efforts to assist workers, including counseling, rehabilitation and employee assistance programs, to conduct such additional research as is necessary to assess the impact and extent of drug abuse and remediation efforts, and submit the findings of such collection and research to Congress no later than two years from Oct. 27, 1986.

INTERAGENCY COORDINATION

Pub. L. 99–570, title IV, § 4304, Oct. 27, 1986, 100 Stat. 3207–154, provided that:

''(a) The Secretary of Education, the Secretary of Health and Human Services, and the Secretary of Labor shall each designate an officer or employee of the Departments of Education, Health and Human Services, and Labor, respectively, to coordinate interagency drug abuse prevention activities to prevent duplication of effort.

''(b) Within one year after enactment of this Act [Oct. 27, 1986], a report shall be jointly submitted to the Congress by such Secretaries concerning the extent to which States and localities have been able to implement non-duplicative drug abuse prevention activities.''

SUBSTANCE ABUSE COVERAGE STUDY

Pub. L. 99–570, title VI, § 6005, Oct. 27, 1986, 100 Stat. 3207–160, as amended by Pub. L. 100–690, title II, § 2058(c), Nov. 18, 1988, 102 Stat. 4214, directed Secretary of Health and Human Services to contract with Institute of Medicine of National Academy of Sciences to conduct a study of extent to which cost of drug abuse treatment is covered by private insurance, public programs, and other sources of payment, and adequacy of such coverage for the rehabilitation of drug abusers, and not later than 18 months after execution of such contract to transmit to Congress a report of results of study, including recommendations of means to meet the needs identified in such study.

HEALTH INSURANCE COVERAGE FOR DRUG AND ALCOHOL TREATMENT

Pub. L. 99–570, title VI, § 6006, Oct. 27, 1986, 100 Stat. 3207–160, provided that:

''(a) FINDINGS.—The Congress finds that—

''(1) drug and alcohol abuse are problems of grave concern and consequence in American society;

''(2) over 500,000 individuals are known heroin addicts; 5 million individuals use cocaine; and at least 7 million individuals regularly use prescription drugs, mostly addictive ones, without medical supervision;

''(3) 10 million adults and 3 million children and adolescents abuse alcohol, and an additional 30 to 40 million people are adversely affected because of close family ties to alcoholics;

''(4) the total cost of drug abuse to the Nation in 1983 was over $60,000,000,000; and

''(5) the vast majority of health benefits plans provide only limited coverage for treatment of drug and alcohol addiction, which is a fact that can discourage the abuser from seeking treatment or, if the abuser does seek treatment, can cause the abuser to face significant out of pocket expenses for the treatment.

''(b) SENSE OF CONGRESS.—It is the sense of Congress that—

''(1) all employers providing health insurance policies should ensure that the policies provide adequate coverage for treatment of drug and alcohol addiction in recognition that the health consequences and costs for individuals and society can be as formidable as those resulting from other diseases and illnesses for which insurance coverage is much more adequate; and

''(2) State insurance commissioners should encourage employers providing health benefits plans to ensure that the policies provide more adequate coverage for treatment of drug and alcohol addiction.''

COMMISSION ON MARIHUANA AND DRUG ABUSE

Section 601 of Pub. L. 91–513, as amended by Pub. L. 92–13, May 14, 1971, 85 Stat. 37, provided that:

''(a) [ESTABLISHMENT; COMPOSITION] There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the 'Commission'). The Commission shall be composed of—

''(1) two Members of the Senate appointed by the President of the Senate;

''(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

''(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

''(b) [CHAIRMAN; VICE CHAIRMAN; COMPENSATION OF MEMBERS; MEETINGS] (1) The President shall designate one of the members of the Commission as Chairman and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

''(2) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties.

''(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

''(c) [PERSONNEL; EXPERTS; INFORMATION FROM DEPARTMENTS AND AGENCIES] (1) The Commission shall

have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

''(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including traveltime. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

''(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

''(d) [MARIHUANA STUDY; REPORT TO THE PRESIDENT AND THE CONGRESS] (1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas:

''(A) the extent of use of marihuana in the United States to include its various sources of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

''(B) an evaluation of the efficacy of existing marihuana laws;

''(C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;

''(D) the relationship of marihuana use to aggressive behavior and crime;

''(E) the relationship between marihuana and the use of other drugs; and

''(F) the international control of marihuana.

''(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations.

''(e) [STUDY AND INVESTIGATION OF CAUSES OF DRUG ABUSE; REPORT TO THE PRESIDENT AND THE CONGRESS; TERMINATION OF COMMISSION] The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

''(f) [LIMITATION ON EXPENDITURES] Total expenditures of the Commission shall not exceed $4,000,000.''

EXECUTIVE ORDER NO. 11599

Ex. Ord. No. 11599, June 17, 1971, 36 F.R. 11793, which established the Special Action Office for Drug Abuse Prevention, was superseded. See Prior Provisions notes set out under section 1111 of this title.

EXECUTIVE ORDER NO. 11641

Ex. Ord. No. 11641, Jan. 28, 1972, 37 F.R. 2421, which established the Office for Drug Abuse Law Enforcement, was revoked by Ex. Ord. No. 11727, July 6, 1973, 38 F.R. 18357, set out below.

EXECUTIVE ORDER NO. 11676

Ex. Ord. No. 11676, July 27, 1972, 37 F.R. 15125, which established the Office of National Narcotics Intelligence, was revoked by Ex. Ord. No. 11727, July 6, 1973, 38 F.R. 18357, set out below.

EX. ORD. NO. 11727. DRUG LAW ENFORCEMENT

Ex. Ord. No. 11727, July 6, 1973, 38 F.R. 18357, provided:

Reorganization Plan No. 2 of 1973 [set out in the Appendix to Title 5, Government Organization and Employees], which becomes effective on July 1, 1973, among other things establishes a Drug Enforcement Administration in the Department of Justice. In my message to the Congress transmitting that plan, I stated that all functions of the Office for Drug Abuse Law Enforcement (established pursuant to Executive Order No. 11641 of January 28, 1972) and the Office of National Narcotics Intelligence (established pursuant to Executive Order No. 11676 of July 27, 1972) would, together with other related functions, be merged in the new Drug Enforcement Administration.

NOW, THEREFORE, by virtue of the authority vested in me by the Constitution and laws of the United States, including section 5317 of title 5 of the United States Code, as amended, it is hereby ordered as follows:

SECTION 1. The Attorney General, to the extent permitted by law, is authorized to coordinate all activities of executive branch departments and agencies which are directly related to the enforcement of laws respecting narcotics and dangerous drugs. Each department and agency of the Federal Government shall, upon request and to the extent permitted by law, assist the Attorney General in the performance of functions assigned to him pursuant to this order, and the Attorney General may, in carrying out those functions, utilize the services of any other agencies, Federal and State, as may be available and appropriate.

SEC. 2. Executive Order No. 11641 of January 28, 1972, is revoked and the Attorney General shall provide for the reassignment of the functions of the Office for Drug Abuse Law Enforcement and for the abolishment of that Office.

SEC. 3. Executive Order No. 11676 of July 27, 1972, is hereby revoked and the Attorney General shall provide for the reassignment of the functions of the Office of National Narcotics Intelligence and for the abolishment of that Office.

SEC. 4. Section 1 of Executive Order No. 11708 of March 23, 1973, as amended [set out as a note under section 5317 of Title 5, Government Organization and Employees], placing certain positions in level IV of the Executive Schedule is hereby further amended by deleting—

(1) ''(6) Director, Office for Drug Abuse Law Enforcement, Department of Justice.''; and

(2) ''(7) Director, Office of National Narcotics Intelligence, Department of Justice.''

SEC. 5. The Attorney General shall provide for the winding up of the affairs of the two offices and for the reassignment of their functions.

SEC. 6. This order shall be effective as of July 1, 1973.

RICHARD NIXON.

ACT REFERRED TO IN OTHER SECTIONS

The Chemical Diversion and Trafficking Act of 1988 is referred to in title 18 section 1956.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 15 section 1456.

## § 801a. Congressional findings and declarations: psychotropic substances

The Congress makes the following findings and declarations:

(1) The Congress has long recognized the danger involved in the manufacture, distribution, and use of certain psychotropic substances for nonscientific and nonmedical purposes, and has provided strong and effective legislation to control illicit trafficking and to regulate legitimate uses of psychotropic substances in this country. Abuse of psychotropic substances has become a phenomenon common to many countries, however, and is not confined to national borders. It is, therefore, essential that the United States cooperate with other nations in establishing effective controls over international traffic in such substances.

(2) The United States has joined with other countries in executing an international treaty, entitled the Convention on Psychotropic Substances and signed at Vienna, Austria, on February 21, 1971, which is designed to establish suitable controls over the manufacture, distribution, transfer, and use of certain psychotropic substances. The Convention is not self-executing, and the obligations of the United States thereunder may only be performed pursuant to appropriate legislation. It is the intent of the Congress that the amendments made by this Act, together with existing law, will enable the United States to meet all of its obligations under the Convention and that no further legislation will be necessary for that purpose.

(3) In implementing the Convention on Psychotropic Substances, the Congress intends that, consistent with the obligations of the United States under the Convention, control of psychotropic substances in the United States should be accomplished within the framework of the procedures and criteria for classification of substances provided in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.]. This will insure that (A) the availability of psychotropic substances to manufacturers, distributors, dispensers, and researchers for useful and legitimate medical and scientific purposes will not be unduly restricted; (B) nothing in the Convention will interfere with bona fide research activities; and (C) nothing in the Convention will interfere with ethical medical practice in this country as determined by the Secretary of Health and Human Services on the basis of a consensus of the views of the American medical and scientific community.

(Pub. L. 95–633, title I, § 101, Nov. 10, 1978, 92 Stat. 3768; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

REFERENCES IN TEXT

This Act, referred to in par. (2), is Pub. L. 95–633, Nov. 10, 1978, 92 Stat. 2768, as amended, known as the Psychotropic Substances Act of 1978, which enacted sections 801a, 830, and 852 of this title, amended sections 352, 802, 811, 812, 823, 827, 841 to 843, 872, 881, 952, 953, and 965 of this title and section 242a of Title 42, The Public Health and Welfare, repealed section 830 of this title effective Jan. 1, 1981, and enacted provisions set out as notes under sections 801, 801a, 812, and 830 of this title. For complete classification of this Act to the Code, see Short Title of 1978 Amendment note set out under section 801 of this title and Tables.

The Comprehensive Drug Abuse Prevention and Control Act of 1970, referred to in par. (3), is Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236, as amended, which is classified principally to this chapter [§ 801 et seq.]. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

CODIFICATION

Section was enacted as a part of the Psychotropic Substances Act of 1978, and not as a part of the Controlled Substances Act which comprises this subchapter.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in par. (3) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE

Section 112 of title I of Pub. L. 95–633 provided that: ''This title [enacting this section and section 852 of this title, amending sections 352, 802, 811, 812, 823, 827, 872, 952, and 953 of this title and section 242a of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 801 and 812 of this title] and the amendments made by this title shall take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on February 21, 1971, enters into force in respect to the United States.'' [The Convention entered into force in respect to the United States on July 15, 1980.]

## § 802. Definitions

As used in this subchapter:

(1) The term ''addict'' means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term ''administer'' refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term ''agent'' means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term ''Drug Enforcement Administration'' means the Drug Enforcement Administration in the Department of Justice.

(5) The term ''control'' means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term ''controlled substance'' means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

(7) The term ''counterfeit substance'' means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms ''deliver'' or ''delivery'' mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term ''depressant or stimulant substance'' means—

(A) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid; or (ii) any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 352(d) of this title; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous systems; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term ''dispense'' means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term ''dispenser'' means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term ''distribute'' means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term ''distributor'' means a person who so delivers a controlled substance or a listed chemical.

(12) The term ''drug'' has the meaning given that term by section 321(g)(1) of this title.

(13) The term ''felony'' means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term ''isomer'' means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term ''isomer'' means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term ''isomer'' means any optical or geometric isomer.

(15) The term ''manufacture'' means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term ''manufacturer'' means a person who manufactures a drug or other substance.

(16) The term ''marihuana'' means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term ''narcotic drug'' means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term ''opiate'' means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term ''opium poppy'' means the plant of the species Papaver somniferum L., except the seed thereof.

(20) The term ''poppy straw'' means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term ''practitioner'' means a physician, dentist, veterinarian, scientific investiga-

tor, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term ''production'' includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term ''immediate precursor'' means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term ''Secretary'', unless the context otherwise indicates, means the Secretary of Health and Human Services.

(25) The term ''serious bodily injury'' means bodily injury which involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term ''State'' means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.

(27) The term ''ultimate user'' means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term ''United States'', when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term ''maintenance treatment'' means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term ''detoxification treatment'' means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term ''Convention on Psychotropic Substances'' means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term ''Single Convention on Narcotic Drugs'' means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (B), the term ''controlled substance analogue'' means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 355 of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term ''listed chemical'' means any list I chemical or any list II chemical.

(34) The term ''list I chemical'' means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.

(B) Benzyl cyanide.

(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.

(D) Ergonovine and its salts.

(E) Ergotamine and its salts.

(F) N-Acetylanthranilic acid, its esters, and its salts.

(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(H) Phenylacetic acid, its esters, and its salts.

(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(J) Piperidine and its salts.

(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(L) 3,4-Methylenedioxyphenyl-2-propanone.

(M) Methylamine.

(N) Ethylamine.

(O) Propionic anhydride.

(P) Insosafrole.

(Q) Safrole.

(R) Piperonal.
(S) N-Methylepherdrine.[1]
(T) N-methylpseudoephedrine.
(U) Hydriotic[2] acid.
(V) Benzaldehyde.
(W) Nitroethane.
(X) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term ''list II chemical'' means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:
(A) Acetic anhydride.
(B) Acetone.
(C) Benzyl chloride.
(D) Ethyl ether.
(E) Repealed. Pub. L. 101–647, title XXIII, § 2301(b), Nov. 29, 1990, 104 Stat. 4858.
(F) Potassium permanganate.
(G) 2-Butanone.
(H) Toluene.

(36) The term ''regular customer'' means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term ''regular importer'' means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term ''regulated person'' means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term ''regulated transaction'' means—

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 830 of this title;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) unless—

(I)(aa) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient; or

(bb) the Attorney General has determined under section 814 of this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General; or

(v) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term ''chemical mixture'' means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)(A) The term ''anabolic steroid'' means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes—
(i) boldenone,
(ii) chlorotestosterone,
(iii) clostebol,
(iv) dehydrochlormethyltestosterone,

[1] So in original. Probably should be ''N-Methylephedrine.''
[2] So in original. Probably should be ''Hydriodic''.

(v) dihydrotestosterone,
(vi) drostanolone,
(vii) ethylestrenol,
(viii) fluoxymesterone,
(ix) formebulone,
(x) mesterolone,
(xi) methandienone,
(xii) methandranone,
(xiii) methandriol,
(xiv) methandrostenolone,
(xv) methenolone,
(xvi) methyltestosterone,
(xvii) mibolerone,
(xviii) nandrolone,
(xix) norethandrolone,
(xx) oxandrolone,
(xxi) oxymesterone,
(xxii) oxymetholone,
(xxiii) stanolone,
(xxiv) stanozolol,
(xxv) testolactone,
(xxvi) testosterone,
(xxvii) trenbolone, and
(xxviii) any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.

(B)(i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(42) The term ''international transaction'' means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms ''broker'' and ''trader'' mean a person that assists in arranging an international transaction in a listed chemical by—

(A) negotiating contracts;
(B) serving as an agent or intermediary; or
(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(43)[3] The term ''felony drug offense'' means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, or depressant or stimulant substances.

(Pub. L. 91–513, title II, § 102, Oct. 27, 1970, 84 Stat. 1242; Pub. L. 93–281, § 2, May 14, 1974, 88 Stat. 124; Pub. L. 95–633, title I, § 102(b), Nov. 10, 1978, 92 Stat. 3772; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 96–132, § 16(a), Nov. 30, 1979, 93 Stat. 1049; Pub. L. 98–473, title II, § 507(a), (b), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 98–509, title III, § 301(a), Oct. 19, 1984, 98 Stat. 2364; Pub. L. 99–514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 99–570, title I, §§ 1003(b), 1203, 1870, Oct. 27, 1986, 100 Stat. 3207–6, 3207–13, 3207–56; Pub. L. 99–646, § 83, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 100–690, title VI, § 6054, Nov. 18, 1988, 102 Stat. 4316; Pub. L. 101–647, title XIX, § 1902(b), title XXIII, § 2301, title XXXV, § 3599I, Nov. 29, 1990, 104 Stat. 4852, 4858, 4932; Pub. L. 103–200, §§ 2(a), 7–9(a), Dec. 17, 1993, 107 Stat. 2333, 2340; Pub. L. 103–322, title IX, § 90105(d), title XXXIII, § 330024(a), (b), (d)(1), Sept. 13, 1994, 108 Stat. 1988, 2150.)

[3] So in original. Probably should be ''(44)''.

REFERENCES IN TEXT

This subchapter, referred to in introductory provisions and in par. (39)(A)(iii), (v), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Schedules I, II, III, IV, and V, referred to in pars. (6), (14), and (32)(A), are set out in section 812(c) of this title.

Subchapter II of this chapter, referred to in par. (39)(A)(iii), (v), was in the original ''title III'', meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in par. (39)(A)(iv), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

AMENDMENTS

1994—Par. (34)(V), (W). Pub. L. 103–322, § 330024(b), realigned margins and capitalized first letter.

Par. (35). Pub. L. 103–322, § 330024(d)(1), made technical correction to directory language of Pub. L. 103–200, § 2(a)(4)(B). See 1993 Amendment note below.

Par. (39)(A)(iv)(II). Pub. L. 103–322, § 330024(a), substituted ''; or'' for period at end.

Par. (43). Pub. L. 103–322, § 90105(d), added par. (43) defining ''felony drug offense''.

1993—Par. (33). Pub. L. 103–200, § 2(a)(1), substituted ''any list I chemical or any list II chemical'' for ''any listed precursor chemical or listed essential chemical''.

Par. (34). Pub. L. 103–200, § 2(a)(2), substituted ''list I chemical'' for ''listed precursor chemical'' and ''important to the manufacture'' for ''critical to the creation'' in introductory provisions.

Par. (34)(A), (F), (H). Pub. L. 103–200, § 2(a)(3), inserted '', its esters,'' before ''and''.

Par. (34)(O). Pub. L. 103–200, § 8(1), (2), redesignated subpar. (P) as (O) and struck out former subpar. (O) which read as follows: ''D-lysergic acid.''

Par. (34)(P) to (S). Pub. L. 103–200, § 8(2), redesignated subpars. (Q) to (T) as (P) to (S), respectively. Former subpar. (P) redesignated (O).

Par. (34)(T). Pub. L. 103–200, § 8(2), redesignated subpar. (V) as (T). Former subpar. (T) redesignated (S).

Par. (34)(U). Pub. L. 103–200, § 8(1), (2), redesignated subpar. (X) as (U) and struck out former subpar. (U) which read as follows: ''N-ethylephedrine.''

Par. (34)(V). Pub. L. 103–200, § 8(2), (4), added subpar. (V) and redesignated former subpar. (V) as (T).

Par. (34)(W). Pub. L. 103–200, § 8(1), (4), added subpar. (W) and struck out former subpar. (W) which read as follows: ''N-ethylpseudoephedrine.''

Par. (34)(X). Pub. L. 103–200, § 8(2), (3), redesignated subpar. (Y) as (X) and substituted ''through (U)'' for ''through (X)''.

Par. (34)(Y). Pub. L. 103–200, § 8(2), redesignated subpar. (Y) as (X).

Par. (35). Pub. L. 103–200, § 2(a)(4)(A), (C), substituted ''list II chemical'' for ''listed essential chemical'' and struck out ''as a solvent, reagent, or catalyst'' before ''in manufacturing''.

Pub. L. 103–200, § 2(a)(4)(B), as amended by Pub. L. 103–322, § 330024(d)(1), inserted ''(other than a list I chemical)'' before ''specified'' the first time appearing.

Par. (37). Pub. L. 103–200, § 9(a), amended par. (37) generally. Prior to amendment, par. (37) read as follows: ''The term 'regular supplier' means, with respect to a regulated person, a supplier with whom the regulated person has an established business relationship that is reported to the Attorney General.''

Par. (38). Pub. L. 103–200, § 2(a)(5), inserted before period at end ''or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine''.

Par. (39)(A). Pub. L. 103–200, §§ 2(a)(6)(A), 7, in introductory provisions, substituted ''importation, or exportation of, or an international transaction involving shipment of,'' for ''importation or exportation of'' and inserted ''a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical,'' before ''a threshold amount,''.

Par. (39)(A)(iii). Pub. L. 103–200, § 2(a)(6)(B), inserted ''or any category of transaction for a specific listed chemical or chemicals'' after ''transaction''.

Par. (39)(A)(iv). Pub. L. 103–200, § 2(a)(6)(C), amended cl. (iv) generally. Prior to amendment, cl. (iv) read as follows: ''any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act; or''.

Par. (39)(A)(v). Pub. L. 103–200, § 2(a)(6)(D), inserted before semicolon at end ''which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered''.

Par. (40). Pub. L. 103–200, § 2(a)(7), substituted ''list I chemical or a list II chemical'' for ''listed precursor chemical or a listed essential chemical'' in two places.

Pars. (42), (43). Pub. L. 103–200, § 2(a)(8), added pars. (42) and (43).

1990—Par. (32)(A). Pub. L. 101–647, § 3599I, substituted ''the stimulant'' for ''the stimulent'' in cl. (ii) and ''a stimulant'' for ''a stimulent'' in cl. (iii).

Par. (34)(M) to (Y). Pub. L. 101–647, § 2301(a), added subpars. (M) to (Y).

Par. (35)(E). Pub. L. 101–647, § 2301(b), struck out subpar. (E) ''Hydriodic acid.''

Par. (41). Pub. L. 101–647, § 1902(b), added par. (41).

1988—Par. (8). Pub. L. 100–690, § 6054(1), inserted ''or a listed chemical'' after ''a controlled substance''.

Par. (11). Pub. L. 100–690, § 6054(2), inserted ''or a listed chemical'' after ''a controlled substance'' in two places.

Pars. (33) to (40). Pub. L. 100–690, § 6054(3), added pars. (33) to (40).

1986—Par. (6). Pub. L. 99–514 substituted ''Internal Revenue Code of 1986'' for ''Internal Revenue Code of 1954''.

Par. (14). Pub. L. 99–570, § 1870, and Pub. L. 99–646 amended par. (14) identically, substituting ''any optical'' for ''the optical'' in second and third sentences.

Par. (25). Pub. L. 99–570, § 1003(b)(1), added par. (25). Former par. (25) redesignated (26).

Pars. (26) to (31). Pub. L. 99–570, § 1003(b)(2), redesignated pars. (25) to (30) as (26) to (31), respectively.

Par. (32). Pub. L. 99–570, § 1203, added par. (32).

1984—Pars. (14) to (16). Pub. L. 98–473, § 507(a), added par. (14) and redesignated former pars. (14) to (16) as (15) to (17), respectively.

Par. (17). Pub. L. 98–473, § 507, redesignated former par. (16) as (17), and expanded and revised definition of ''narcotic drug'', including within term poppy straw, cocaine, and ecgonine. Former par. (17) redesignated (18).

Pars. (18) to (28). Pub. L. 98–473, § 507(a), redesignated former pars. (17) to (27) as (18) to (28), respectively.

Par. (29). Pub. L. 98–509 which directed the substitution of ''one hundred and eighty'' for ''twenty-one'' in par. (28), was executed to par. (29) in view of the redesignation of par. (28) as par. (29) by Pub. L. 98–473.

Pub. L. 98–473, § 507(a), redesignated former par. (28) as (29). Former par. (29) redesignated (30).

Par. (30). Pub. L. 98–473, § 507(a), redesignated former par. (29) as (30).

1979—Par. (4). Pub. L. 96–132 substituted provisions defining ''Drug Enforcement Administration'' for provisions defining ''Bureau of Narcotics and Dangerous Drugs''.

1978—Par. (29). Pub. L. 95–633 added par. (29).

1974—Pars. (27), (28). Pub. L. 93–281 added pars. (27) and (28).

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in par. (24) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1994 AMENDMENT

Section 330024(f) of Pub. L. 103–322 provided that: ''The amendments made by this section [amending this section and sections 824, 960, and 971 of this title] shall take effect as of the date that is 120 days after the date of enactment of the Domestic Chemical Diversion Control Act of 1993 [Dec. 17, 1993].''

EFFECTIVE DATE OF 1993 AMENDMENT

Section 11 of Pub. L. 103–200 provided that: ''This Act [enacting section 814 of this title, amending this section and sections 821 to 824, 830, 843, 880, 957, 958, 960, and 971 of this title, and enacting provisions set out as a note under section 801 of this title] and the amendments made by this Act shall take effect on the date that is 120 days after the date of enactment of this Act [Dec. 17, 1993].''

EFFECTIVE DATE OF 1990 AMENDMENT

Section 1902(d) of Pub. L. 101–647 provided that: ''This section [amending this section and section 812 of this title and enacting provisions set out as a note under section 829 of this title] and the amendment made by this section shall take effect 90 days after the date of enactment of this Act [Nov. 29, 1990].''

EFFECTIVE DATE OF 1988 AMENDMENT

Section 6061 of title VI of Pub. L. 100–690 provided that: ''Except as otherwise provided in this subtitle, this subtitle [subtitle A (§§ 6051–6061) of title VI of Pub. L. 100–690, enacting section 971 of this title, amending this section and sections 830, 841 to 843, 872, 876, 881, 960, and 961 of this title, and enacting provisions set out as notes under this section and section 971 of this title] shall take effect 120 days after the enactment of this Act [Nov. 18, 1988].''

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

REGULATIONS

Section 301(b) of Pub. L. 98–509 provided that: ''The Secretary of Health and Human Services shall, within ninety days of the date of the enactment of this Act [Oct. 19, 1984], promulgate regulations for the administration of section 102(28) of the Controlled Substances Act [21 U.S.C. 802(29)] as amended by subsection (a) and shall include in the first report submitted under section 505(b) [now 503(b)] of the Public Health Service Act

[42 U.S.C. 290aa–2(b)] after the expiration of such ninety days the findings of the Secretary with respect to the effect of the amendment made by subsection (a).''

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

EXEMPTION FOR SUBSTANCES IN PARAGRAPH (41)

Section 1903 of Pub. L. 101–647 provided that:

''(a) ABUSE POTENTIAL.—The Attorney General, upon the recommendation of the Secretary of Health and Human Services, may, by regulation, exempt any compound, mixture, or preparation containing a substance in paragraph (41) of section 102 of the Controlled Substances Act [21 U.S.C. 802(41)] (as added by section 2 [1902] of this Act) from the application of all or any part of the Controlled Substances Act [21 U.S.C. 801 et seq.] if, because of its concentration, preparation, mixture or delivery system, it has no significant potential for abuse.

''(b) DRUGS FOR TREATMENT OF RARE DISEASES.—If the Attorney General finds that a drug listed in paragraph (41) of section 102 of the Controlled Substances Act (as added by section 2 [1902] of this Act) is—

''(1) approved by the Food and Drug Administration as an accepted treatment for a rare disease or condition, as defined in section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb); and

''(2) does not have a significant potential for abuse, the Attorney General may exempt such drug from any production regulations otherwise issued under the Controlled Substances Act as may be necessary to ensure adequate supplies of such drug for medical purposes.

''(c) DATE OF ISSUANCE OF REGULATIONS.—The Attorney General shall issue regulations implementing this section not later than 45 days after the date of enactment of this Act [Nov. 29, 1990], except that the regulations required under section 3(a) [1903(a)] shall be issued not later than 180 days after the date of enactment of this Act.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 814, 822, 823, 830, 889, 951, 957, 958, 967, 1115, 1507 of this title; title 7 sections 2015, 2021; title 8 sections 1101, 1182, 1251; title 16 section 559b; title 18 sections 342, 521, 842, 922, 924, 1791, 1952, 1961, 2118, 3142, 3563, 3592; title 19 sections 1401, 1584, 1607; title 22 sections 2291, 2714; title 23 section 410; title 28 section 2901; title 29 section 1111; title 42 sections 201, 1437d, 1437f, 2000e–2, 2473c, 3411, 3602, 3607, 5667, 5667a, 11851, 11905, 11924, 12602; title 46 section 2101; title 46 App. section 1903; title 48 sections 1902, 1903; title 49 sections 5331, 20140, 30301, 31102, 31301, 31306, 44106, 44111, 44703, 44710, 44713, 45101, 46306, 80302.

## § 803. Repealed. Pub. L. 95–137, § 1(b), Oct. 18, 1977, 91 Stat. 1169

Section, Pub. L. 91–513, title II, § 103, Oct. 27, 1970, 84 Stat. 1245, authorized Bureau of Narcotics and Dangerous Drugs to add, during fiscal year 1971, 300 agents, together with necessary supporting personnel, and provided for appropriations of $6,000,000 to carry out such addition.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

## § 811. Authority and criteria for classification of substances

### (a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

### (b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

**(c) Factors determinative of control or removal from schedules**

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

**(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances**

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a ''schedule notice'') that existing legal controls applicable under this subchapter to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services after consultation with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall—

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of

the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)(A) If the Attorney General determines, after consultation with the Secretary of Health and Human Services, that proceedings initiated under recommendations made under paragraph[1] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)—

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

**(e) Immediate precursors**

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule,

[1] So in original. Probably should be ''subparagraph''.

other substances shall not be placed in a schedule solely because they are its precursors.

**(f) Abuse potential**

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

**(g) Exclusion of non-narcotic substances sold over the counter without a prescription; dextromethorphan; exemption of substances lacking abuse potential**

(1) The Attorney General shall by regulation exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

**(h) Temporary scheduling to avoid imminent hazards to public safety**

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355]. Such an order may not be issued before the expiration of thirty days from—

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling for up to six months.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) of this section with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

(Pub. L. 91–513, title II, §201, Oct. 27, 1970, 84 Stat. 1245; Pub. L. 95–633, title I, §102(a), Nov. 10, 1978, 92 Stat. 3769; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 98–473, title II, §§508, 509(a), Oct. 12, 1984, 98 Stat. 2071, 2072.)

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (a), (c)(8), (d)(3), (4)(A), (B), and (g)(2), (3), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (d)(3) and (g)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

Schedules I, IV, and V, referred to in subsecs. (d)(4)(A), (B), and (h)(1), are set out in section 812(c) of this title.

The Psychotropic Substances Act of 1978, referred to in subsec. (d)(5), is Pub. L. 95–633, Nov. 10, 1978, 92 Stat. 3768, which enacted sections 801a, 830, and 852 of this title, amended sections 352, 802, 811, 812, 823, 827, 841 to 843, 872, 881, 952, 953, and 965 of this title and section 242a of Title 42, The Public Health and Welfare, repealed section 830 of this title effective Jan. 1, 1981, and enacted provisions set out as notes under sections 801, 801a, 812, and 830 of this title. For complete classification of this Act to the Code, see Short Title of 1978 Amendment note set out under section 801 of this title and Tables.

AMENDMENTS

1984—Subsec. (g)(3). Pub. L. 98–473, §509(a), added par. (3).

Subsec. (h). Pub. L. 98–473, § 508, added subsec. (h).

1978—Subsec. (d). Pub. L. 95–633 designated existing provisions as par. (1) and added pars. (2) to (5).

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsec. (d)(2), (3), (4)(A), (B), (5) pursuant to section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 812, 872, 1115 of this title.

## § 812. Schedules of controlled substances

### (a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

### (b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

### (c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended[1] pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol.[2]
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.

[1] Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

[2] So in original. Probably should be ''Alphacetylmethadol.''

(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.
(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Propheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salt of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-diamethoxyamphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols.

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.
(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.
(3) Opium poppy and poppy straw.
(4) coca[3] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:
(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any

[3] So in original. Probably should be capitalized.

quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.

(3) Glutehimide.

(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

SCHEDULE IV

(1) Barbital.

(2) Chloral betaine.

(3) Chloral hydrate.

(4) Ethchlorvynol.

(5) Ethinamate.

(6) Methohexital.

(7) Meprobamate.

(8) Methylphenobarbital.

(9) Paraldehyde.

(10) Petrichloral.

(11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(Pub. L. 91–513, title II, § 202, Oct. 27, 1970, 84 Stat. 1247; Pub. L. 95–633, title I, § 103, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, §§ 507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub. L. 99–570, title I, § 1867, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, § 84, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 101–647, title XIX, § 1902(a), Nov. 29, 1990, 104 Stat. 4851.)

AMENDMENTS

1990—Subsec. (c). Pub. L. 101–647 added item (e) at end of schedule III.

1986—Subsec. (c). Pub. L. 99–646 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: ''Coca leaves (except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed); cocaine, its salts, optical and geometric isomers, and salts of isomers; and ecgonine, its derivatives, their salts, isomers, and salts of isomers.''

Pub. L. 99–570 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: ''Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.''

1984—Subsec. (c). Pub. L. 98–473, § 507(c), in schedule II(a)(4) added applicability to cocaine and ecgonine and their salts, isomers, etc.

Subsec. (d). Pub. L. 98–473, § 509(b), struck out subsec. (d) which related to authority of Attorney General to except stimulants or depressants containing active medicinal ingredients.

1978—Subsec. (d)(3). Pub. L. 95–633 added cl. (3).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–647 effective 90 days after Nov. 29, 1990, see section 1902(d) of Pub. L. 101–647, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

PLACEMENT OF PIPRADROL AND SPA IN SCHEDULE IV TO CARRY OUT OBLIGATION UNDER CONVENTION ON PSYCHOTROPIC SUBSTANCES

Section 102(c) of Pub. L. 95–633 provided that: ''For the purpose of carrying out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections 201 and 202 of the Controlled Substances Act [this section and section 811 of this title], place such drugs in schedule IV of such Act [see subsec. (c) of this section].''

Provision of section 102(c) of Pub. L. 95–633, set out above, effective on the date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 811, 1115 of this title; title 10 section 912a; title 19 section 2484; title 29 sections 706, 2006; title 41 section 706; title 42 sections 12111, 12210.

## § 813. Treatment of controlled substance analogues

A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I.

(Pub. L. 91–513, title II, § 203, as added Pub. L. 99–570, title I, § 1202, Oct. 27, 1986, 100 Stat. 3207–13; amended Pub. L. 100–690, title VI, § 6470(c), Nov. 18, 1988, 102 Stat. 4378.)

REFERENCES IN TEXT

Schedule I, referred to in text, is set out in section 812(c) of this title.

AMENDMENTS

1988—Pub. L. 100–690 substituted ''any Federal law'' for ''this subchapter and subchapter II of this chapter''.

## § 814. Removal of exemption of certain drugs

### (a) Removal of exemption

The Attorney General shall by regulation remove from exemption under section 802(39)(A)(iv) of this title a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

### (b) Factors to be considered

In removing a drug or group of drugs from exemption under subsection (a) of this section, the Attorney General shall consider, with respect to a drug or group of drugs that is proposed to be removed from exemption—

(1) the scope, duration, and significance of the diversion;

(2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) whether the listed chemical can be readily recovered from the drug or group of drugs.

### (c) Specificity of designation

The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) of this section to the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

### (d) Reinstatement of exemption with respect to particular drug products

#### (1) Reinstatement

On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a) of this section, the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

#### (2) Factors to be considered

In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider—

(A) the package sizes and manner of packaging of the drug product;

(B) the manner of distribution and advertising of the drug product;

(C) evidence of diversion of the drug product;

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) of this section as applied to the drug product.

#### (3) Status pending application for reinstatement

A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) of this section shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—

(A) the Attorney General has evidence that, applying the factors described in subsection (b) of this section to the drug product, the drug product is being diverted; and

(B) the Attorney General so notifies the applicant.

**(4) Amendment and modification**

A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product upon a finding that—

(A) applying the factors described in subsection (b) of this section to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

(Pub. L. 91–513, title II, § 204, as added Pub. L. 103–200, § 2(b)(1), Dec. 17, 1993, 107 Stat. 2334.)

EFFECTIVE DATE

Section effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as an Effective Date of 1993 Amendment note under section 802 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 802 of this title.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

PART REFERRED TO IN OTHER SECTIONS

This part is referred to in section 811 of this title; title 48 section 1972.

## § 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions.

(Pub. L. 91–513, title II, § 301, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 103–200, § 3(a), Dec. 17, 1993, 107 Stat. 2336.)

AMENDMENTS

1993—Pub. L. 103–200 inserted before period at end ''and to the registration and control of regulated persons and of regulated transactions''.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

## § 822. Persons required to register

**(a) Period of registration**

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

**(b) Authorized activities**

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

**(c) Exceptions**

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802(25)[1] of this title.

**(d) Waiver**

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

**(e) Separate registration**

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

**(f) Inspection**

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(Pub. L. 91–513, title II, § 302, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 98–473, title II, § 510, Oct. 12, 1984, 98 Stat. 2072; Pub. L. 103–200, § 3(b), Dec. 17, 1993, 107 Stat. 2336.)

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (b) and (c), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Section 802(25) of this title, referred to in subsec. (c)(3), was redesignated section 802(26) of this title by Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071, and was further redesignated section 802(27) of this title by Pub. L. 99–570, title I, § 1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.

[1] See References in Text note below.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–200, § 3(b)(1), inserted ''or list I chemical'' after ''controlled substance'' in two places.

Subsec. (b). Pub. L. 103–200, § 3(b)(2), inserted ''or list I chemicals'' after ''controlled substances'' and ''or chemicals'' after ''such substances''.

Subsec. (c). Pub. L. 103–200, § 3(b)(3), inserted ''or list I chemical'' after ''controlled substance'' wherever appearing.

Subsec. (e). Pub. L. 103–200, § 3(b)(4), inserted ''or list I chemicals'' after ''controlled substances''.

1984—Subsec. (a). Pub. L. 98–473 designated existing provisions as par. (1), struck out provisions relating to dispensing controlled substances, and added par. (2).

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

PROVISIONAL REGISTRATION

Section 703 of Pub. L. 91–513, as amended by Pub. L. 99–514, § 2, Oct. 22, 1986, 100 Stat. 2095, provided that:

''(a)(1) Any person who—

''(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [this section], and

''(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4722 of Title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [section 823 of this title] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

''(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [section 360 of this title] or under such section 4722 [section 4722 of Title 26] (as the case may be) shall be his registration number for purposes of section 303 of this title [section 823 of this title].

''(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

''(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

''(1) the date on which such person has registered with the Attorney General under section 303 [section 823 of this title] or has had his registration denied under such section, or

''(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 827, 828, 880, 958, 965 of this title; title 18 section 2118.

## § 823. Registration requirements

### (a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

### (b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

### (c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

### (d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the pub-

lic interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

**(e) Distributors of controlled substances in schedule III, IV, or V**

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

**(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances**

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

**(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications**

Practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

**(h) Applicants for distribution of list I chemicals**

The Attorney General shall register an applicant to distribute a list I chemical unless the

Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 802(39)(A)(iv) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(Pub. L. 91–513, title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 93–281, § 3, May 14, 1974, 88 Stat. 124; Pub. L. 95–633, title I, § 109, Nov. 10, 1978, 92 Stat. 3773; Pub. L. 98–473, title II, § 511, Oct. 12, 1984, 98 Stat. 2073; Pub. L. 103–200, § 3(c), Dec. 17, 1993, 107 Stat. 2336.)

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a) to (f), are set out in section 812(c) of this title.

AMENDMENTS

1993—Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984—Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978—Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974—Subsec. (g). Pub. L. 93–281 added subsec. (g).

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 824, 827, 828, 880, 952, 958, 965 of this title.

## § 824. Denial, revocation, or suspension of registration

### (a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(g) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g) of this title.

### (b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

### (c) Service of show cause order; proceedings

Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

### (d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with

the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

**(e) Suspension and revocation of quotas**

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

**(f) Disposition of controlled substances or list I chemicals**

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

**(g) Seizure or placement under seal of controlled substances or list I chemicals**

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(Pub. L. 91–513, title II, § 304, Oct. 27, 1970, 84 Stat. 1255; Pub. L. 93–281, § 4, May 14, 1974, 88 Stat. 125; Pub. L. 98–473, title II, §§ 304, 512, 513, Oct. 12, 1984, 98 Stat. 2050, 2073; Pub. L. 100–93, § 8(j), Aug. 18, 1987, 101 Stat. 695; Pub. L. 103–200, § 3(d), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103–322, title XXXIII, § 330024(e), Sept. 13, 1994, 108 Stat. 2151.)

REFERENCES IN TEXT

This subchapter, referred to in subsec. (a)(1), (2), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Subchapter II of this chapter, referred to in subsec. (a)(1), (2), was in the original ''title III'', meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

1994—Subsec. (g). Pub. L. 103–322 inserted ''or chemical'' after ''such substance'' in last sentence.

1993—Subsec. (a). Pub. L. 103–200, § 3(d)(1), inserted ''or a list I chemical'' after ''controlled substance'' in introductory provisions and par. (2) and inserted ''or list I chemicals'' after ''controlled substances'' in par. (3).

Subsec. (b). Pub. L. 103–200, § 3(d)(2), inserted ''or list I chemical'' after ''controlled substance''.

Subsec. (f). Pub. L. 103–200, § 3(d)(3), inserted ''or list I chemicals'' after ''controlled substances'' wherever appearing.

Subsec. (g). Pub. L. 103–200, § 3(d)(4), inserted ''or list I chemicals'' after ''controlled substances'' in two places and ''or list I chemical'' after ''controlled substance'' wherever appearing.

1987—Subsec. (a)(5). Pub. L. 100–93 added par. (5).

1984—Subsec. (a)(3). Pub. L. 98–473, § 512(1), inserted provisions relating to suspension, etc., recommended by competent State authority.

Subsec. (a)(4). Pub. L. 98–473, § 512(2), added par. (4).

Subsec. (f). Pub. L. 98–473, § 304, inserted provisions relating to vesting of right, title, and interest in the United States.

Subsec. (g). Pub. L. 98–473, § 513, added subsec. (g).

1974—Subsec. (a). Pub. L. 93–281, § 4(a), provided for revocation or suspension of a registration pursuant to section 823(g) of this title for failure of a registrant to comply with standards referred to in such section 823(g).

Subsec. (d). Pub. L. 93–281, § 4(b), substituted ''A suspension under this subsection'' for ''Such suspension'' in third sentence.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub. L. 103–322, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of Title 42, The Public Health and Welfare.

PROVISIONAL REGISTRATION

Applicability of this section to provisional registrations, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 823, 842 of this title; title 42 sections 1320a–7, 11152.

### § 825. Labeling and packaging

#### (a) Symbol

It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 321(k) of this title) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

#### (b) Unlawful distribution without identifying symbol

It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 321(m) of this title) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a) of this section.

#### (c) Warning on label

The Secretary shall prescribe regulations under section 353(b) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

#### (d) Containers to be securely sealed

It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

(Pub. L. 91–513, title II, § 305, Oct. 27, 1970, 84 Stat. 1256.)

REFERENCES IN TEXT

Schedules I, II, III, and IV, referred to in subsecs. (c) and (d), are set out in section 812(c) of this title.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91–513, set out as a note under section 801 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 842, 958 of this title.

### § 826. Production quotas for controlled substances

#### (a) Establishment of total annual needs

The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

#### (b) Individual production quotas; revised quotas

The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a) of this section. The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

#### (c) Manufacturing quotas for registered manufacturers

On or before October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

#### (d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years

The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

#### (e) Quota increases

At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the re-

mainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

**(f) Incidental production exception**

Notwithstanding any other provisions of this subchapter, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance with respect to which its manufacturer is duly registered under this subchapter. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances.

(Pub. L. 91–513, title II, § 306, Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94–273, § 3(16), Apr. 21, 1976, 90 Stat. 377.)

REFERENCES IN TEXT

Schedules I and II, referred to in text, are set out in section 812(c) of this title.

AMENDMENTS

1976—Subsec. (c). Pub. L. 94–273 substituted ''October'' for ''July''.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91–513, set out as a note under section 801 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 823, 824, 842 of this title.

## § 827. Records and reports of registrants

**(a) Inventory**

Except as provided in subsection (c) of this section—

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

**(b) Availability of records**

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

**(c) Nonapplicability**

The foregoing provisions of this section shall not apply—

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)(A) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 355(i) or 360b(j) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this subchapter.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or

otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.

**(d) Periodic reports to Attorney General**

Every manufacturer registered under section 823 of this title shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under section 822(d) of this title) to whom such sale, delivery, or other disposal was made.

**(e) Reporting and recordkeeping requirements of drug conventions**

In addition to the reporting and recordkeeping requirements under any other provision of this subchapter, each manufacturer registered under section 823 of this title shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this subchapter on manufacturers subject to the requirements of this subsection.

**(f) Investigational uses of drugs; procedures**

Regulations under sections 355(i) and 360(j) of this title, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

**(g) Change of address**

Every registrant under this subchapter shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

(Pub. L. 91–513, title II, § 307, Oct. 27, 1970, 84 Stat. 1258; Pub. L. 93–281, § 5, May 14, 1974, 88 Stat. 125; Pub. L. 95–633, title I, §§ 104, 110, Nov. 10, 1978, 92 Stat. 3772, 3773; Pub. L. 98–473, title II, §§ 514, 515, Oct. 12, 1984, 98 Stat. 2074.)

REFERENCES IN TEXT

Schedules II, III, IV, and V, referred to in subsec. (c), are set out in section 812(c) of this title.

AMENDMENTS

1984—Subsec. (c)(1)(A). Pub. L. 98–473, § 514(a), substituted "to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual" for "with respect to any narcotic controlled substance in schedule II, III, IV, or V, to the prescribing or administering of such substance by a practitioner in the lawful course of his professional practice unless such substance was prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual".

Subsec. (c)(1)(B). Pub. L. 98–473, § 514(b), substituted "to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual" for "with respect to nonnarcotic controlled substances in schedule II, III, IV, or V, to any practitioner who dispenses such substances to his patients, unless the practitioner is regularly engaged in charging his patients, either separately or together with charges for other professional services, for substances so dispensed".

Subsec. (g). Pub. L. 98–473, § 515, added subsec. (g).

1978—Subsec. (c). Pub. L. 95–633, § 110, inserted provision following par. (3) relating to the construction of the Convention on Psychotropic Substances.

Subsecs. (e), (f). Pub. L. 95–633 added subsec. (e) and redesignated former subsec. (e) as (f).

1974—Subsec. (c)(1)(A). Pub. L. 93–281 substituted "any narcotic controlled substance" for "narcotic controlled substances" and made section applicable to any narcotic controlled substance prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 823, 829, 902, 958 of this title.

## § 828. Order forms

**(a) Unlawful distribution of controlled substances**

It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section.

**(b) Nonapplicability of provisions**

Nothing in subsection (a) of this section shall apply to—

(1) the exportation of such substances from the United States in conformity with subchapter II of this chapter;

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a) of this section.

**(c) Preservation and availability**

(1) Every person who in pursuance of an order required under subsection (a) of this section dis-

tributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

(2) Every person who gives an order required under subsection (a) of this section shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

**(d) Issuance**

(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) of this section only to persons validly registered under section 823 of this title (or exempted from registration under section 822(d) of this title). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith.

**(e) Unlawful acts**

It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

(Pub. L. 91–513, title II, § 308, Oct. 27, 1970, 84 Stat. 1259.)

REFERENCES IN TEXT

Schedules I and II, referred to in subsec. (a), are set out in section 812(c) of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 843 of this title.

## § 829. Prescriptions

**(a) Schedule II substances**

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

**(b) Schedule III and IV substances**

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

**(c) Schedule V substances**

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

**(d) Non-prescription drugs with abuse potential**

Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(Pub. L. 91–513, title II, § 309, Oct. 27, 1970, 84 Stat. 1260.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a), (b), and (d), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

Schedules II, III, IV, and V, referred to in subsecs. (a) to (c), are set out in section 812(c) of this title.

EFFECT OF SCHEDULING ON PRESCRIPTIONS

Pub. L. 101–647, title XIX, § 1902(c), Nov. 29, 1990, 104 Stat. 4852, provided that: ''Any prescription for anabolic steroids subject to refill on or after the date of enactment of the amendments made by this section [Nov. 29, 1990] may be refilled without restriction under section 309(a) of the Controlled Substances Act (21 U.S.C. 829(a)).''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 842, 902 of this title.

## § 830. Regulation of listed chemicals and certain machines

**(a) Record of regulated transactions**

(1) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction—

(A) for 4 years after the date of the transaction, if the listed chemical is a list I chemical or if the transaction involves a tableting machine or an encapsulating machine; and

(B) for 2 years after the date of the transaction, if the listed chemical is a list II chemical.

(2) A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. Such record shall be available for inspection and copying by the Attorney General.

(3) It is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

**(b) Reports to Attorney General**

(1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation—

(A) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this subchapter;

(B) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(C) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(D) any regulated transaction in a tableting machine or an encapsulating machine.

Each report under subparagraph (A) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved. A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (B) unless the transaction is approved by the Attorney General. The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under subparagraph (A) and subparagraph (C).

(2) A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person. The requirement of the preceding sentence shall not apply to the manufacture of a drug product that is exempted under section 802(39)(A)(iv) of this title.

**(c) Confidentiality of information obtained by Attorney General; non-disclosure; exceptions**

(1) Except as provided in paragraph (2), any information obtained by the Attorney General under this section which is exempt from disclosure under section 552(a) of title 5, by reason of section 552(b)(4) of such title, is confidential and may not be disclosed to any person.

(2) Information referred to in paragraph (1) may be disclosed only—

(A) to an officer or employee of the United States engaged in carrying out this subchapter, subchapter II of this chapter, or the customs laws;

(B) when relevant in any investigation or proceeding for the enforcement of this subchapter, subchapter II of this chapter, or the customs laws;

(C) when necessary to comply with an obligation of the United States under a treaty or other international agreement; or

(D) to a State or local official or employee in conjunction with the enforcement of controlled substances laws or chemical control laws.

(3) The Attorney General shall—

(A) take such action as may be necessary to prevent unauthorized disclosure of information by any person to whom such information is disclosed under paragraph (2); and

(B) issue guidelines that limit, to the maximum extent feasible, the disclosure of proprietary business information, including the names or identities of United States exporters of listed chemicals, to any person to whom such information is disclosed under paragraph (2).

(4) Any person who is aggrieved by a disclosure of information in violation of this section may bring a civil action against the violator for appropriate relief.

(5) Notwithstanding paragraph (4), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

(Pub. L. 91–513, title II, § 310, as added Pub. L. 95–633, title II, § 202(a), Nov. 10, 1978, 92 Stat. 3774; amended Pub. L. 100–690, title VI, § 6052(a), Nov. 18, 1988, 102 Stat. 4312; Pub. L. 103–200, §§ 2(c), 10, Dec. 17, 1993, 107 Stat. 2336, 2341.)

REFERENCES IN TEXT

Subchapter II of this chapter, referred to in subsec. (c)(2)(A), (B), was in the original ''title III'', meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

The customs laws, referred to in subsec. (c)(2)(A), (B), are classified generally to Title 19, Customs Duties.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–200, § 2(c)(1), substituted ''list I chemical'' for ''precursor chemical'' in subpar. (A) and ''a list II chemical'' for ''an essential chemical'' in subpar. (B).

Subsec. (b). Pub. L. 103–200, § 10, designated existing provisions as par. (1), redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, in concluding provisions, substituted ''subparagraph (A)'' for ''paragraph (1)'' in two places, ''subparagraph (B)'' for ''para-

graph (2)'', and ''subparagraph (C)'' for ''paragraph (3)'', and added par. (2).

Subsec. (c)(2)(D). Pub. L. 103–200, § 2(c)(2), substituted ''chemical control laws'' for ''precursor chemical laws''.

1988—Pub. L. 100–690 amended section generally, substituting provisions relating to regulation of listed chemicals and certain machines for provisions relating to reporting by any person who distributes, sells, or imports any piperidine.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

EFFECTIVE DATE; TIME TO SUBMIT PIPERIDINE REPORT; REQUIRED INFORMATION

Section 203(a) of title II of Pub. L. 95–633 provided that:

''(1) Except as provided under paragraph (2), the amendments made by this title [enacting this section and amending sections 841 to 843 of this title] shall take effect on the date of the enactment of this Act [Nov. 10, 1978].

''(2) Any person required to submit a report under section 310(a)(1) of the Controlled Substances Act [subsec. (a)(1) of this section] respecting a distribution, sale, or importation of piperidine during the 90 days after the date of the enactment of this Act [Nov. 10, 1978] may submit such report any time up to 97 days after such date of enactment.

''(3) Until otherwise provided by the Attorney General by regulation, the information required to be reported by a person under section 310(a)(1) of the Controlled Substances Act (as added by section 202(a)(2) of this title) [subsec. (a)(1) of this section] with respect to the person's distribution, sale, or importation of piperidine shall—

''(A) be the information described in subparagraphs (A) and (B) of such section, and

''(B) except as provided in paragraph (2) of this subsection, be reported not later than seven days after the date of such distribution, sale, or importation.''

REPEALS

Pub. L. 96–359, § 8(b), Sept. 26, 1980, 94 Stat. 1194, repealed section 203(d) of Pub. L. 95–633, which had provided for the repeal of this section effective Jan. 1, 1981.

REGULATIONS FOR PIPERIDINE REPORTING

Section 203(b) of Pub. L. 95–633 required the Attorney General to publish proposed interim regulations for piperidine reporting under section 830(a) of this title not later than 30 days after enactment, and final interim regulations not later than 75 days after enactment, such final interim regulations to be effective on and after the ninety-first day after enactment.

REPORT TO PRESIDENT AND CONGRESS ON EFFECTIVENESS OF TITLE II OF PUB. L. 95–633

Section 203(c) of Pub. L. 95–633 required the Attorney General to analyze and evaluate the impact and effectiveness of the amendments made by title II of Pub. L. 95–633, and report to the President and Congress not later than Mar. 1, 1980.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 802, 841, 842, 843, 958 of this title.

PART D—OFFENSES AND PENALTIES

## § 841. Prohibited acts A

### (a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

### (b) Penalties

Except as otherwise provided in section 849, 859, 860, or 861 of this title, any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) In the case of a violation of subsection (a) of this section involving—

(i) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 50 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[ 1-(2-phenylethyl)-4-piperidinyl ] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(viii) 100 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 1 kilogram or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life,

a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $8,000,000 if the defendant is an individual or $20,000,000 if the defendant is other than an individual, or both. If any person commits a violation of this subparagraph or of section 849, 859, 860, or 861 of this title after two or more prior convictions for a felony drug offense have become final, such person shall be sentenced to a mandatory term of life imprisonment without release and fined in accordance with the preceding sentence. Any sentence under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(B) In the case of a violation of subsection (a) of this section involving—

(i) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) 500 grams or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 5 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[ 1-(2-phenylethyl)-4-piperidinyl ] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100 or more marihuana plants regardless of weight; or

(viii) 10 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 100 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Any sentence imposed under this subparagraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(C) In the case of a controlled substance in schedule I or II except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term

of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil or in the case of any controlled substance in schedule III, such person shall, except as provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 3 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 6 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $100,000 if the defendant is an individual or $250,000 if the defendant is other than an individual, or both. If any person commits such a violation after one or more convictions of him for an offense punishable under this paragraph, or for a crime under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $200,000 if the defendant is an individual or $500,000 if the defendant is other than an individual, or both.

(4) Notwithstanding paragraph (1)(D) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in section 844 of this title and section 3607 of title 18.

(5) Any person who violates subsection (a) of this section by cultivating a controlled substance on Federal property shall be imprisoned as provided in this subsection and shall be fined any amount not to exceed—

(A) the amount authorized in accordance with this section;

(B) the amount authorized in accordance with the provisions of title 18;

(C) $500,000 if the defendant is an individual; or

(D) $1,000,000 if the defendant is other than an individual;

or both.

(6) Any person who violates subsection (a) of this section, or attempts to do so, and knowingly or intentionally uses a poison, chemical, or other hazardous substance on Federal land, and, by such use—

(A) creates a serious hazard to humans, wildlife, or domestic animals,

(B) degrades or harms the environment or natural resources, or

(C) pollutes an aquifer, spring, stream, river, or body of water,

shall be fined in accordance with title 18 or imprisoned not more than five years, or both.

**(c) Repealed. Pub. L. 98–473, title II, § 224(a)(2), formerly § 224(a)(6), Oct. 12, 1984, 98 Stat. 2030, as renumbered by Pub. L. 99–570, title I, § 1005(a)(2), Oct. 27, 1986, 100 Stat. 3207–6**

**(d) Offenses involving listed chemicals**

Any person who knowingly or intentionally—

(1) possesses a listed chemical with intent to manufacture a controlled substance except as authorized by this subchapter;

(2) possesses or distributes a listed chemical knowing, or having reasonable cause to be-

lieve, that the listed chemical will be used to manufacture a controlled substance except as authorized by this subchapter; or

(3) with the intent of causing the evasion of the recordkeeping or reporting requirements of section 830 of this title, or the regulations issued under that section, receives or distributes a reportable amount of any listed chemical in units small enough so that the making of records or filing of reports under that section is not required;

shall be fined in accordance with title 18 or imprisoned not more than 10 years, or both.

**(e) Boobytraps on Federal property; penalties; "boobytrap" defined**

(1) Any person who assembles, maintains, places, or causes to be placed a boobytrap on Federal property where a controlled substance is being manufactured, distributed, or dispensed shall be sentenced to a term of imprisonment for not more than 10 years and shall be fined not more than $10,000.

(2) If any person commits such a violation after 1 or more prior convictions for an offense punishable under this subsection, such person shall be sentenced to a term of imprisonment of not more than 20 years and shall be fined not more than $20,000.

(3) For the purposes of this subsection, the term ''boobytrap'' means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of any unsuspecting person making contact with the device. Such term includes guns, ammunition, or explosive devices attached to trip wires or other triggering mechanisms, sharpened stakes, and lines or wires with hooks attached.

**(f) Ten-year injunction as additional penalty**

In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, or importation of a listed chemical may be enjoined from engaging in any regulated transaction involving a listed chemical for not more than ten years.

**(g) Wrongful distribution or possession of listed chemicals**

(1) Whoever knowingly distributes a listed chemical in violation of this subchapter (other than in violation of a recordkeeping or reporting requirement of section 830 of this title) shall be fined under title 18 or imprisoned not more than 5 years, or both.

(2) Whoever possesses any listed chemical, with knowledge that the recordkeeping or reporting requirements of section 830 of this title have not been adhered to, if, after such knowledge is acquired, such person does not take immediate steps to remedy the violation shall be fined under title 18 or imprisoned not more than one year, or both.

(Pub. L. 91–513, title II, §401, Oct. 27, 1970, 84 Stat. 1260; Pub. L. 95–633, title II, §201, Nov. 10, 1978, 92 Stat. 3774; Pub. L. 96–359, §8(c), Sept. 26, 1980, 94 Stat. 1194; Pub. L. 98–473, title II, §§224(a), 502, 503(b)(1), (2), Oct. 12, 1984, 98 Stat. 2030, 2068, 2070; Pub. L. 99–570, title I, §§1002, 1003(a), 1004(a), 1005(a), 1103, title XV, §15005, Oct. 27, 1986, 100 Stat. 3207–2, 3207–5, 3207–6, 3207–11, 3702–192; Pub. L. 100–690, title VI, §§6055, 6254(h), 6452(a), 6470(g), (h), 6479, Nov. 18, 1988, 102 Stat. 4318, 4367, 4371, 4378, 4381; Pub. L. 101–647, title X, §1002(e), title XII, §1202, title XXXV, §3599K, Nov. 29, 1990, 104 Stat. 4828, 4830, 4932; Pub. L. 103–322, title IX, §90105(a), (c), title XVIII, §180201(b)(2)(A), Sept. 13, 1994, 108 Stat. 1987, 1988, 2047.)

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (a), (b)(1) to (3), (d)(1), (2), and (g)(1), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Schedules I, II, III, IV, and V, referred to in subsec. (b), are set out in section 812(c) of this title.

Subchapter II of this chapter, referred to in subsec. (b)(1) to (3), was in the original ''title III'', meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

1994—Subsec. (b). Pub. L. 103–322, §180201(b)(2)(A), inserted ''849,'' before ''859,'' in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 103–322, §§90105(c), 180201(b)(2)(A), in concluding provisions, inserted ''849,'' before ''859,'' and struck out ''For purposes of this subparagraph, the term 'felony drug offense' means an offense that is a felony under any provision of this subchapter or any other Federal law that prohibits or restricts conduct relating to narcotic drugs, marihuana, or depressant or stimulant substances or a felony under any law of a State or a foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, or depressant or stimulant substances.'' before ''Any sentence under this subparagraph''.

Subsec. (b)(1)(B). Pub. L. 103–322, §90105(a), in sentence in concluding provisions beginning ''If any person commits'', substituted ''a prior conviction for a felony drug offense has become final'' for ''one or more prior convictions for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final''.

Subsec. (b)(1)(C). Pub. L. 103–322, §90105(a), in sentence beginning ''If any person commits'', substituted ''a prior conviction for a felony drug offense has become final'' for ''one or more prior convictions for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final''.

Subsec. (b)(1)(D). Pub. L. 103–322, §90105(a), in sentence beginning ''If any person commits'', substituted ''a prior conviction for a felony drug offense has become final'' for ''one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final''.

1990—Subsec. (b). Pub. L. 101–647, §1002(e)(1), substituted ''section 859, 860, or 861'' for ''section 845, 845a, or 845b'' in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 101–647, §1002(e)(1), substituted ''section 859, 860, or 861'' for ''section 845, 845a, or 845b'' in concluding provisions.

Subsec. (b)(1)(A)(ii)(IV). Pub. L. 101–647, § 3599K, substituted ''any of the substances'' for ''any of the substance''.

Subsec. (b)(1)(A)(viii). Pub. L. 101–647, § 1202, substituted ''or 1 kilogram or more of a mixture or substance containing a detectable amount of methamphetamine'' for ''or 100 grams or more of a mixture or substance containing a detectable amount of methamphetamine''.

Subsec. (b)(1)(B)(ii)(IV). Pub. L. 101–647, § 3599K, substituted ''any of the substances'' for ''any of the substance''.

Subsec. (c). Pub. L. 101–647, § 1002(e)(2), directed amendment of subsec. (c) by substituting ''section 859, 860, or 861 of this title'' for ''section 845, 845a, or 845b of this title''. Subsec. (c) was previously repealed by Pub. L. 98–473, § 224(a)(2), as renumbered by Pub. L. 99–570, § 1005(a), effective Nov. 1, 1987, and applicable only to offenses committed after the taking effect of such amendment. See 1984 Amendment note and Effective Date of 1984 Amendment note below.

1988—Subsec. (b)(1)(A). Pub. L. 100–690, §§ 6452(a), 6470(g), 6479(1), inserted '', or 1,000 or more marihuana plants regardless of weight'' in cl. (vii), added cl. (viii), substituted ''a prior conviction for a felony drug offense has become final'' for ''one or more prior convictions for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final'' in second sentence, and added provisions relating to sentencing for a person who violates this subpar. or section 485, 485a, or 485b of this title after two or more prior convictions for a felony drug offense have become final and defining ''felony drug offense''.

Subsec. (b)(1)(B). Pub. L. 100–690, §§ 6470(h), 6479(2), inserted '', or 100 or more marihuana plants regardless of weight'' in cl. (vii) and added cl. (viii).

Subsec. (b)(1)(D). Pub. L. 100–690, § 6479(3), substituted ''50 or more marihuana plants'' for ''100 or more marihuana plants''.

Subsec. (b)(6). Pub. L. 100–690, § 6254(h), added par. (6).

Subsec. (d). Pub. L. 100–690, § 6055(a), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows: ''Any person who knowingly or intentionally—

''(1) possesses any piperidine with intent to manufacture phencyclidine except as authorized by this subchapter, or

''(2) possesses any piperidine knowing, or having reasonable cause to believe, that the piperidine will be used to manufacture phencyclidine except as authorized by this subchapter,

shall be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both.''

Subsecs. (f), (g). Pub. L. 100–690, § 6055(b), added subsecs. (f) and (g).

1986—Pub. L. 99–570, § 1005(a), amended Pub. L. 98–473, § 224(a). See 1984 Amendment note below.

Subsec. (b). Pub. L. 99–570, § 1103(a), substituted '', 845a, or 845b'' for ''or 845a'' in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 99–570, § 1002(2), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''In the case of a violation of subsection (a) of this section involving—

''(i) 100 grams or more of a controlled substance in schedule I or II which is a mixture or substance containing a detectable amount of a narcotic drug other than a narcotic drug consisting of—

''(I) coca leaves;

''(II) a compound, manufacture, salt, derivative, or preparation of coca leaves; or

''(III) a substance chemically identical thereto;

''(ii) a kilogram or more of any other controlled substance in schedule I or II which is a narcotic drug;

''(iii) 500 grams or more of phencyclidine (PCP); or

''(iv) 5 grams or more of lysergic acid diethylamide (LSD);

such person shall be sentenced to a term of imprisonment of not more than 20 years, a fine of not more than $250,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 40 years, a fine of not more than $500,000, or both''.

Subsec. (b)(1)(B). Pub. L. 99–570, § 1002(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''In the case of a controlled substance in schedule I or II except as provided in subparagraphs (A) and (C),, such person shall be sentenced to a term of imprisonment of not more than 15 years, a fine of not more than $125,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 30 years, a fine of not more than $250,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 6 years in addition to such term of imprisonment.''

Subsec. (b)(1)(C). Pub. L. 99–570, § 1002(2), added subpar. (C). Former subpar. (C) redesignated (D).

Subsec. (b)(1)(D). Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term'' in two places.

Pub. L. 99–570, §§ 1002(1), 1003(a)(1), redesignated former subpar. (C) as (D), substituted ''a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual'' for ''a fine of not more than $50,000'' and ''a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual'' for ''a fine of not more than $100,000'', and inserted ''except in the case of 100 or more marihuana plants regardless of weight,''.

Subsec. (b)(2). Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term'' in two places.

Pub. L. 99–570, § 1003(a)(2), substituted ''a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual'' for ''a fine of not more than $25,000'' and ''a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual'' for ''a fine of not more than $50,000''.

Subsec. (b)(3). Pub. L. 99–570, § 1003(a)(3), substituted ''a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $100,000 if the defendant is an individual or $250,000 if the defendant is other than an individual'' for ''a fine of not more than $10,000'' and ''a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $200,000 if the defendant is an individual or $500,000 if the defendant is other than an individual'' for ''a fine of not more than $20,000''.

Subsec. (b)(4). Pub. L. 99–570, § 1003(a)(4), which directed the substitution of ''1(D)'' for ''1(C)'' was exe-

cuted by substituting ''(1)(D)'' for ''(1)(C)'' as the probable intent of Congress.

Subsec. (b)(5). Pub. L. 99–570, § 1003(a)(5), amended par. (5) generally. Prior to amendment, par. (5) read as follows: ''Notwithstanding paragraph (1), any person who violates subsection (a) of this section by cultivating a controlled substance on Federal property shall be fined not more than—

''(A) $500,000 if such person is an individual; and

''(B) $1,000,000 if such person is not an individual.''

Subsec. (c). Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term'' wherever appearing, effective Nov. 1, 1987, the effective date of the repeal of subsec. (c) by Pub. L. 98–473, § 224(a)(2). See 1984 Amendment note below.

Pub. L. 99–570, § 1103(b), substituted '', 845a, or 845b'' for ''845a'' in two places.

Subsec. (d). Pub. L. 99–570, § 1003(a)(6), substituted ''a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual'' for ''a fine of not more than $15,000''.

Subsec. (e). Pub. L. 99–570, § 15005, added subsec. (e).

1984—Subsec. (b). Pub. L. 98–473, § 503(b)(1), inserted reference to section 845a of this title in provisions preceding par. (1)(A).

Pub. L. 98–473, § 224(a)(1)–(3), (5), which directed amendment of this subsection effective Nov. 1, 1987 (see section 235(a)(1) of Pub. L. 98–473 set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure) was repealed by Pub. L. 99–570, § 1005(a), and the remaining pars. (4) and (6) of Pub. L. 98–473, § 224(a), were redesignated as pars. (1) and (2), respectively.

Subsec. (b)(1)(A). Pub. L. 98–473, § 502(1)(A), added subpar. (A). Former subpar. (A) redesignated (B).

Subsec. (b)(1)(B). Pub. L. 98–473, § 502(1)(A), (B), redesignated former subpar. (A) as (B), substituted ''except as provided in subparagraphs (A) and (C),'' for ''which is a narcotic drug'', ''$125,000'' for ''$25,000'', and ''$250,000'' for ''$50,000'', and inserted references to laws of a State and a foreign country. Former subpar. (B) redesignated (C).

Subsec. (b)(1)(C). Pub. L. 98–473, § 502(1)(A), (C), redesignated former subpar. (B) as (C), substituted ''less than 50 kilograms of marihuana, 10 kilograms of hashish, or one kilogram of hashish oil'' for ''a controlled substance in schedule I or II which is not a narcotic drug'', ''and (5)'' for '', (5), and (6)'', ''$50,000'' for ''$15,000'', and ''$100,000'' for ''$30,000'', and inserted references to laws of a State and a foreign country.

Subsec. (b)(2). Pub. L. 98–473, § 502(2), substituted ''$25,000'' for ''$10,000'' and ''$50,000'' for ''$20,000'', and inserted references to laws of a State or of a foreign country.

Subsec. (b)(3). Pub. L. 98–473, § 502(3), substituted ''$10,000'' for ''$5,000'' and ''$20,000'' for ''$10,000'', and inserted references to laws of a State or of a foreign country.

Subsec. (b)(4). Pub. L. 98–473, § 502(4), substituted ''(1)(C)'' for ''(1)(B)''.

Pub. L. 98–473, § 224(a)(1), as renumbered by Pub. L. 99–570, § 1005(a), substituted ''in section 844 of this title and section 3607 of title 18'' for ''in subsections (a) and (b) of section 844 of this title''.

Subsec. (b)(5). Pub. L. 98–473, § 502(5), (6), added par. (5) and struck out former par. (5) which related to penalties for manufacturing, etc., phencyclidine.

Subsec. (b)(6). Pub. L. 98–473, § 502(5), struck out par. (6) which related to penalties for violations involving a quantity of marihuana exceeding 1,000 pounds.

Subsec. (c). Pub. L. 98–473, § 224(a)(2), as renumbered by Pub. L. 99–570, § 1005(a), struck out subsec. (c) which read as follows: ''A special parole term imposed under this section or section 845, 845a, or 845b of this title may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. A special parole term provided for in this section or section 845, 845a, or 845b of this title shall be in addition to, and not in lieu of, any other parole provided for by law.''

Pub. L. 98–473, § 503(b)(2), inserted reference to section 845a of this title in two places.

1980—Subsec. (b)(1)(B). Pub. L. 96–359, § 8(c)(1), inserted reference to par. (6) of this subsection.

Subsec. (b)(6). Pub. L. 96–359, § 8(c)(2), added par. (6).

1978—Subsec. (b)(1)(B). Pub. L. 95–633, § 201(1), inserted '', except as provided in paragraphs (4) and (5) of this subsection,'' after ''such person shall''.

Subsec. (b)(5). Pub. L. 95–633, § 201(2), added par. (5).

Subsec. (d). Pub. L. 95–633, § 201(3), added subsec. (d).

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by section 6055 of Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Section 1004(b) of Pub. L. 99–570 provided that: ''The amendments made by this section [amending this section and sections 845, 845a, 960, and 962 of this title] shall take effect on the date of the taking effect of section 3583 of title 18, United States Code [Nov. 1, 1987].''

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 224(a) of Pub. L. 98–473 effective Nov. 1, 1987, and applicable only to offenses committed after the taking effect of such amendment, see section 235(a)(1) of Pub. L. 98–473, set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective Nov. 10, 1978, see section 203(a) of Pub. L. 95–633 set out as an Effective Date note under section 830 of this title.

REPEALS

Pub. L. 96–359, § 8(b), Sept. 26, 1980, 94 Stat. 1194, repealed section 203(d) of Pub. L. 95–633, which had provided for the repeal of subsec. (d) of this section effective Jan. 1, 1981.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 844a, 848, 849, 859, 860, 861, 886 of this title; title 16 section 559c, 559d; title 18 sections 36, 3553, 3599, 5032, 5038; title 28 section 994.

## § 842. Prohibited acts B

### (a) Unlawful acts

It shall be unlawful for any person—

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration,

order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824(f) or 881 of this title or to remove or dispose of substances so placed under seal;

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection, or to use to his own advantage or reveal (other than as authorized by section 830 of this title) any information that is confidential under such section;

(9) who is a regulated person to engage in a regulated transaction without obtaining the identification required by 830(a)(3) of this title; or

(10) to fail to keep a record or make a report under section 830 of this title.

**(b) Manufacture**

It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or

(2) in excess of a quota assigned to him pursuant to section 826 of this title.

**(c) Penalties**

(1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 to enforce this paragraph.

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than $25,000, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of $50,000, or both.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

(Pub. L. 91–513, title II, § 402, Oct. 27, 1970, 84 Stat. 1262; Pub. L. 95–633, title II, § 202(b)(1), (2), Nov. 10, 1978, 92 Stat. 3776; Pub. L. 100–690, title VI, § 6056, Nov. 18, 1988, 102 Stat. 4318.)

REFERENCES IN TEXT

Schedules I and II, referred to in subsec. (b), are set out in section 812(c) of this title.

AMENDMENTS

1988—Subsec. (a)(8). Pub. L. 100–690, § 6056(a), inserted ‘‘, or to use to his own advantage or reveal (other than as authorized by section 830 of this title) any information that is confidential under such section’’ after ‘‘protection’’.

Subsec. (a)(9). Pub. L. 100–690, § 6056(b), amended par. (9) generally. Prior to amendment, par. (9) read as follows: ‘‘to distribute or sell piperidine in violation of regulations established under section 830(a)(2) of this title, respecting presentation of identification.’’

Subsec. (a)(10). Pub. L. 100–690, § 6056(d), added par. (10).

Subsec. (c)(2)(C). Pub. L. 100–690, § 6056(c), struck out subpar. (C) which read as follows: ‘‘Subparagraphs (A) and (B) shall not apply to a violation of subsection (a)(5) of this section with respect to a refusal or failure to make a report required under section 830(a) of this title (relating to piperidine reporting).’’

1978—Subsec. (a)(9). Pub. L. 95–633, § 202(b)(1), added par. (9).

Subsec. (c)(2)(C). Pub. L. 95–633, § 202(b)(2), added subpar. (C).

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective Nov. 10, 1978, see section 203(a) of Pub. L. 95–633 set out as an Effective Date note under section 830 of this title.

REPEALS

Pub. L. 96–359, § 8(b), Sept. 26, 1980, 94 Stat. 1194, repealed section 203(d) of Pub. L. 95–633, which had provided for the repeal of subsecs. (a)(9) and (c)(2)(C) of this section effective Jan. 1, 1981.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 961 of this title.

## § 843. Prohibited acts C

**(a) Unlawful acts**

It shall be unlawful for any person knowingly or intentionally—

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 828 of this title;

(2) to use in the course of the manufacture, distribution, or dispensing of a controlled substance, or to use for the purpose of acquiring or obtaining a controlled substance, a reg-

istration number which is fictitious, revoked, suspended, expired, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4)(A) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter, or (B) to present false or fraudulent identification where the person is receiving or purchasing a listed chemical and the person is required to present identification under section 830(a) of this title;

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance;

(6) to possess any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this subchapter or subchapter II of this chapter;

(7) to manufacture, distribute, export, or import any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this subchapter or subchapter II of this chapter or, in the case of an exportation, in violation of this subchapter or subchapter II of this chapter or of the laws of the country to which it is exported;

(8) to create a chemical mixture for the purpose of evading a requirement of section 830 of this title or to receive a chemical mixture created for that purpose; or

(9) to distribute, import, or export a list I chemical without the registration required by this subchapter or subchapter II of this chapter.

**(b) Communication facility**

It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II of this chapter. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term ''communication facility'' means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication.

**(c) Advertisement**

It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule[1] I controlled substance. As used in this section the term ''advertisement'' includes, in addition to its ordinary meaning, such advertisements as those for a catalog of Schedule[1] I controlled substances and any similar written advertisement that has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule[1] I controlled substance. The term ''advertisement'' does not include material which merely advocates the use of a similar material, which advocates a position or practice, and does not attempt to propose or facilitate an actual transaction in a Schedule[1] I controlled substance.

**(d) Penalties**

Any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine of not more than $30,000, or both; except that if any person commits such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 8 years, a fine of not more than $60,000, or both.

**(e) Additional penalties**

In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, or importation of a listed chemical may be enjoined from engaging in any regulated transaction involving a listed chemical for not more than ten years.

(Pub. L. 91–513, title II, § 403, Oct. 27, 1970, 84 Stat. 1263; Pub. L. 95–633, title II, § 202(b)(3), Nov. 10, 1978, 92 Stat. 3776; Pub. L. 98–473, title II, § 516, Oct. 12, 1984, 98 Stat. 2074; Pub. L. 99–570, title I, § 1866(a), Oct. 27, 1986, 100 Stat. 3207–54; Pub. L. 100–690, title VI, § 6057, Nov. 18, 1988, 102 Stat. 4319; Pub. L. 103–200, § 3(g), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103–322, title IX, § 90106, Sept. 13, 1994, 108 Stat. 1988.)

REFERENCES IN TEXT

Schedules I and II, referred to in subsecs. (a)(1) and (c), are set out in section 812(c) of this title.

AMENDMENTS

1994—Subsecs. (c) to (e). Pub. L. 103–322 added subsec. (c) and redesignated former subsecs. (c) and (d) as (d) and (e), respectively.

1993—Subsec. (a)(6), (7). Pub. L. 103–200, § 3(g)(1), amended pars. (6) and (7) generally. Prior to amendment, pars. (6) and (7) read as follows:

''(6) to possess any three-neck round-bottom flask, tableting machine, encapsulating machine, gelatin cap-

[1] So in original. Probably should not be capitalized.

sule, or equipment specially designed or modified to manufacture a controlled substance, with intent to manufacture a controlled substance except as authorized by this subchapter;

''(7) to manufacture, distribute, or import any three-neck round-bottom flask, tableting machine, encapsulating machine, gelatin capsule, or equipment specially designed or modified to manufacture a controlled substance, knowing that it will be used to manufacture a controlled substance except as authorized by this subchapter; or''.

Subsec. (a)(9). Pub. L. 103–200, § 3(g)(2), (3), added par. (9).

1988—Subsec. (a)(4)(B). Pub. L. 100–690, § 6057(a)(1), substituted ''a listed chemical'' for ''piperidine''.

Subsec. (a)(6) to (8). Pub. L. 100–690, § 6057(a)(2)–(4), added pars. (6) to (8).

Subsec. (d). Pub. L. 100–690, § 6057(b), added subsec. (d).

1986—Subsec. (a)(2). Pub. L. 99–570 substituted a semicolon for the period at end.

1984—Subsec. (a)(2). Pub. L. 98–473 added applicability to dispensing, acquiring, or obtaining a controlled substance, and applicability to an expired number.

1978—Subsec. (a)(4). Pub. L. 95–633, § 202(b)(3), designated existing provisions as subpar. (A) and added subpar. (B).

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective Nov. 10, 1978, except as otherwise provided, see section 203(a) of Pub. L. 95–633, set out as an Effective Date note under section 830 of this title.

REPEALS

Pub. L. 96–359, § 8(b), Sept. 26, 1980, 94 Stat. 1194, repealed section 203(d) of Pub. L. 95–633, which had provided for the repeal of subsec. (a)(4)(B) of this section effective Jan. 1, 1981.

## § 844. Penalties for simple possession

### (a) Unlawful acts; penalties

It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter. Any person who violates this subsection may be sentenced to a term of imprisonment of not more than 1 year, and shall be fined a minimum of $1,000, or both, except that if he commits such offense after a prior conviction under this subchapter or subchapter II of this chapter, or a prior conviction for any drug or narcotic offense chargeable under the law of any State, has become final, he shall be sentenced to a term of imprisonment for not less than 15 days but not more than 2 years, and shall be fined a minimum of $2,500, except, further, that if he commits such offense after two or more prior convictions under this subchapter or subchapter II of this chapter, or two or more prior convictions for any drug or narcotic offense chargeable under the law of any State, or a combination of two or more such offenses have become final, he shall be sentenced to a term of imprisonment for not less than 90 days but not more than 3 years, and shall be fined a minimum of $5,000. Notwithstanding the preceding sentence, a person convicted under this subsection for the possession of a mixture or substance which contains cocaine base shall be imprisoned not less than 5 years and not more than 20 years, and fined a minimum of $1,000, if the conviction is a first conviction under this subsection and the amount of the mixture or substance exceeds 5 grams, if the conviction is after a prior conviction for the possession of such a mixture or substance under this subsection becomes final and the amount of the mixture or substance exceeds 3 grams, or if the conviction is after 2 or more prior convictions for the possession of such a mixture or substance under this subsection become final and the amount of the mixture or substance exceeds 1 gram. The imposition or execution of a minimum sentence required to be imposed under this subsection shall not be suspended or deferred. Further, upon conviction, a person who violates this subsection shall be fined the reasonable costs of the investigation and prosecution of the offense, including the costs of prosecution of an offense as defined in sections 1918 and 1920 of title 28, except that this sentence shall not apply and a fine under this section need not be imposed if the court determines under the provision of title 18 that the defendant lacks the ability to pay.

### (b) Repealed. Pub. L. 98–473, title II, § 219(a), Oct. 12, 1984, 98 Stat. 2027

### (c) "Drug or narcotic offense" defined

As used in this section, the term ''drug or narcotic offense'' means any offense which proscribes the possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell or transfer any substance the possession of which is prohibited under this subchapter.

(Pub. L. 91–513, title II, § 404, Oct. 27, 1970, 84 Stat. 1264; Pub. L. 98–473, title II, § 219, Oct. 12, 1984, 98 Stat. 2027; Pub. L. 99–570, title I, § 1052, Oct. 27, 1986, 100 Stat. 3207–8; Pub. L. 100–690, title VI, §§ 6371, 6480, Nov. 18, 1988, 102 Stat. 4370, 4382; Pub. L. 101–647, title XII, § 1201, title XIX, § 1907, Nov. 29, 1990, 104 Stat. 4829, 4854.)

AMENDMENTS

1990—Subsec. (a). Pub. L. 101–647, § 1907, inserted subsec. (a) designation.

Pub. L. 101–647, § 1201, substituted ''shall be imprisoned not less than 5 years and not more than 20 years, and fined a minimum of $1,000'' for ''shall be fined under title 18 or imprisoned not less than 5 years and not more than 20 years, or both''.

1988—Subsec. (a). Pub. L. 100–690, § 6480(1)(A)–(C), struck out ''but not more than $5,000'' after ''$1,000'', ''but not more than $10,000'' after ''$2,500'', and ''but not more than $25,000'' after ''$5,000'' in second sentence.

Pub. L. 100–690, § 6371, inserted provisions relating to increased penalties in cases of certain serious crack possession offenses, making offenders subject to fines under title 18 or imprisonment to terms not less than 5 years nor more than 20 years, or both.

1986—Subsec. (a). Pub. L. 99–570 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as fol-

lows: ''It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter. Any person who violates this subsection shall be sentenced to a term of imprisonment of not more than one year, a fine of not more than $5,000, or both, except that if he commits such offense after a prior conviction or convictions under this subsection have become final, he shall be sentenced to a term of imprisonment of not more than 2 years, a fine of not more than $10,000 or both.''

Subsec. (b). Pub. L. 99–570, in amending subsec. (b) generally, substituted ''Upon the discharge of such person and dismissal of the proceedings'' for ''Upon the dismissal of such person and discharge of the proceedings'' in par. (2).

Subsec. (c). Pub. L. 99–570, in amending section generally, added subsec. (c).

1984—Pub. L. 98–473 struck out subsec. (a) designation and struck out subsec. (b) which related to probation before judgment and expunging of records for first offense.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–473 effective Nov. 1, 1987, and applicable only to offenses committed after the taking effect of such amendment, see section 235(a)(1) of Pub. L. 98–473, set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 841, 844a, 885 of this title; title 18 sections 3553, 3607.

## § 844a. Civil penalty for possession of small amounts of certain controlled substances

### (a) In general

Any individual who knowingly possesses a controlled substance that is listed in section 841(b)(1)(A) of this title in violation of section 844 of this title in an amount that, as specified by regulation of the Attorney General, is a personal use amount shall be liable to the United States for a civil penalty in an amount not to exceed $10,000 for each such violation.

### (b) Income and net assets

The income and net assets of an individual shall not be relevant to the determination whether to assess a civil penalty under this section or to prosecute the individual criminally. However, in determining the amount of a penalty under this section, the income and net assets of an individual shall be considered.

### (c) Prior conviction

A civil penalty may not be assessed under this section if the individual previously was convicted of a Federal or State offense relating to a controlled substance.

### (d) Limitation on number of assessments

A civil penalty may not be assessed on an individual under this section on more than two separate occasions.

### (e) Assessment

A civil penalty under this section may be assessed by the Attorney General only by an order made on the record after opportunity for a hearing in accordance with section 554 of title 5. The Attorney General shall provide written notice to the individual who is the subject of the proposed order informing the individual of the opportunity to receive such a hearing with respect to the proposed order. The hearing may be held only if the individual makes a request for the hearing before the expiration of the 30-day period beginning on the date such notice is issued.

### (f) Compromise

The Attorney General may compromise, modify, or remit, with or without conditions, any civil penalty imposed under this section.

### (g) Judicial review

If the Attorney General issues an order pursuant to subsection (e) of this section after a hearing described in such subsection, the individual who is the subject of the order may, before the expiration of the 30-day period beginning on the date the order is issued, bring a civil action in the appropriate district court of the United States. In such action, the law and the facts of the violation and the assessment of the civil penalty shall be determined de novo, and shall include the right of a trial by jury, the right to counsel, and the right to confront witnesses. The facts of the violation shall be proved beyond a reasonable doubt.

### (h) Civil action

If an individual does not request a hearing pursuant to subsection (e) of this section and the Attorney General issues an order pursuant to such subsection, or if an individual does not under subsection (g) of this section seek judicial review of such an order, the Attorney General may commence a civil action in any appropriate district court of the United States for the purpose of recovering the amount assessed and an amount representing interest at a rate computed in accordance with section 1961 of title 28. Such interest shall accrue from the expiration of the 30-day period described in subsection (g) of this section. In such an action, the decision of the Attorney General to issue the order, and the amount of the penalty assessed by the Attorney General, shall not be subject to review.

### (i) Limitation

The Attorney General may not under this subsection[1] commence proceeding against an individual after the expiration of the 5-year period beginning on the date on which the individual allegedly violated subsection (a) of this section.

### (j) Expungement procedures

The Attorney General shall dismiss the proceedings under this section against an individual upon application of such individual at any time after the expiration of 3 years if—

(1) the individual has not previously been assessed a civil penalty under this section;

(2) the individual has paid the assessment;

(3) the individual has complied with any conditions imposed by the Attorney General;

(4) the individual has not been convicted of a Federal or State offense relating to a controlled substance; and

(5) the individual agrees to submit to a drug test, and such test shows the individual to be drug free.

[1] So in original. Probably should be ''section''.

A nonpublic record of a disposition under this subsection shall be retained by the Department of Justice solely for the purpose of determining in any subsequent proceeding whether the person qualified for a civil penalty or expungement under this section. If a record is expunged under this subsection, an individual concerning whom such an expungement has been made shall not be held thereafter under any provision of law to be guilty of perjury, false swearing, or making a false statement by reason of his failure to recite or acknowledge a proceeding under this section or the results thereof in response to an inquiry made of him for any purpose.

(Pub. L. 91–513, title II, § 405, formerly Pub. L. 100–690, title VI, § 6486, Nov. 18, 1988, 102 Stat. 4384, renumbered § 405 of Pub. L. 91–513, and amended Pub. L. 101–647, title X, § 1002(g)(1), (2), Nov. 29, 1990, 104 Stat. 4828.)

PRIOR PROVISIONS

A prior section 405 of Pub. L. 91–513 was renumbered section 418 and is classified to section 859 of this title.

AMENDMENTS

1990—Subsec. (a). Pub. L. 101–647, § 1002(g)(2)(A), made technical amendments to references to sections 841(b)(1)(A) and 844 of this title to correct references to corresponding provisions of original act.

Subsecs. (c), (j)(4). Pub. L. 101–647, § 1002(g)(2)(B), (C), struck out ''as defined in section 802 of this title'' after ''controlled substance''.

### §§ 845 to 845b. Transferred

CODIFICATION

Section 845, Pub. L. 91–513, title II, § 405, Oct. 27, 1970, 84 Stat. 1265, as amended, which related to distribution of controlled substances to persons under age twenty-one, was renumbered § 418 of Pub. L. 91–513 by Pub. L. 101–647, title X, § 1002(a)(1), Nov. 29, 1990, 104 Stat. 4827, and transferred to section 859 of this title.

Section 845a, Pub. L. 91–513, title II, § 405A, as added Pub. L. 98–473, title II, § 503(a), Oct. 12, 1984, 98 Stat. 2069, and amended, which related to distribution or manufacturing of controlled substances in or near schools and colleges, was renumbered § 419 of Pub. L. 91–513 by Pub. L. 101–647, title X, § 1002(b), Nov. 29, 1990, 104 Stat. 4827, and transferred to section 860 of this title.

Section 845b, Pub. L. 91–513, title II, § 405B, as added Pub. L. 99–570, title I, § 1102, Oct. 27, 1986, 100 Stat. 3207–10, and amended, which related to employment or use of persons under 18 years of age in drug operations, was renumbered § 420 of Pub. L. 91–513 by Pub. L. 101–647, title X, § 1002(c), Nov. 29, 1990, 104 Stat. 4827, and transferred to section 861 of this title.

### § 846. Attempt and conspiracy

Any person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

(Pub. L. 91–513, title II, § 406, Oct. 27, 1970, 84 Stat. 1265; Pub. L. 100–690, title VI, § 6470(a), Nov. 18, 1988, 102 Stat. 4377.)

AMENDMENTS

1988—Pub. L. 100–690 substituted ''shall be subject to the same penalties as those prescribed for the offense'' for ''is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 18 sections 36, 3553.

### § 847. Additional penalties

Any penalty imposed for violation of this subchapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

(Pub. L. 91–513, title II, § 407, Oct. 27, 1970, 84 Stat. 1265.)

### § 848. Continuing criminal enterprise

**(a) Penalties; forfeitures**

Any person who engages in a continuing criminal enterprise shall be sentenced to a term of imprisonment which may not be less than 20 years and which may be up to life imprisonment, to a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, and to the forfeiture prescribed in section 853 of this title; except that if any person engages in such activity after one or more prior convictions of him under this section have become final, he shall be sentenced to a term of imprisonment which may not be less than 30 years and which may be up to life imprisonment, to a fine not to exceed the greater of twice the amount authorized in accordance with the provisions of title 18 or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, and to the forfeiture prescribed in section 853 of this title.

**(b) Life imprisonment for engaging in continuing criminal enterprise**

Any person who engages in a continuing criminal enterprise shall be imprisoned for life and fined in accordance with subsection (a) of this section, if—

(1) such person is the principal administrator, organizer, or leader of the enterprise or is one of several such principal administrators, organizers, or leaders; and

(2)(A) the violation referred to in subsection (c)(1) of this section involved at least 300 times the quantity of a substance described in subsection 841(b)(1)(B) of this title, or

(B) the enterprise, or any other enterprise in which the defendant was the principal or one of several principal administrators, organizers, or leaders, received $10 million dollars in gross receipts during any twelve-month period of its existence for the manufacture, importation, or distribution of a substance described in section 841(b)(1)(B) of this title.

**(c) "Continuing criminal enterprise" defined**

For purposes of subsection (a) of this section, a person is engaged in a continuing criminal enterprise if—

(1) he violates any provision of this subchapter or subchapter II of this chapter the punishment for which is a felony, and

(2) such violation is a part of a continuing series of violations of this subchapter or subchapter II of this chapter—

(A) which are undertaken by such person in concert with five or more other persons

with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

**(d) Suspension of sentence and probation prohibited**

In the case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended, probation shall not be granted, and the Act of July 15, 1932 (D.C. Code, secs. 24–203—24–207), shall not apply.

**(e) Death penalty**

(1) In addition to the other penalties set forth in this section—

(A) any person engaging in or working in furtherance of a continuing criminal enterprise, or any person engaging in an offense punishable under section 841(b)(1)(A) of this title or section 960(b)(1) of this title who intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of an individual and such killing results, shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death; and

(B) any person, during the commission of, in furtherance of, or while attempting to avoid apprehension, prosecution or service of a prison sentence for, a felony violation of this subchapter or subchapter II of this chapter who intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of any Federal, State, or local law enforcement officer engaged in, or on account of, the performance of such officer's official duties and such killing results, shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death.

(2) As used in paragraph (1)(b),[1] the term ''law enforcement officer'' means a public servant authorized by law or by a Government agency or Congress to conduct or engage in the prevention, investigation, prosecution or adjudication of an offense, and includes those engaged in corrections, probation, or parole functions.

**(g)[2] Hearing required with respect to death penalty**

A person shall be subjected to the penalty of death for any offense under this section only if a hearing is held in accordance with this section.

**(h) Notice by Government in death penalty cases**

(1) Whenever the Government intends to seek the death penalty for an offense under this section for which one of the sentences provided is death, the attorney for the Government, a reasonable time before trial or acceptance by the court of a plea of guilty, shall sign and file with the court, and serve upon the defendant, a notice—

(A) that the Government in the event of conviction will seek the sentence of death; and

(B) setting forth the aggravating factors enumerated in subsection (n) of this section and any other aggravating factors which the Government will seek to prove as the basis for the death penalty.

(2) The court may permit the attorney for the Government to amend this notice for good cause shown.

**(i) Hearing before court or jury**

(1) When the attorney for the Government has filed a notice as required under subsection (h) of this section and the defendant is found guilty of or pleads guilty to an offense under subsection (e) of this section, the judge who presided at the trial or before whom the guilty plea was entered, or any other judge if the judge who presided at the trial or before whom the guilty plea was entered is unavailable, shall conduct a separate sentencing hearing to determine the punishment to be imposed. The hearing shall be conducted—

(A) before the jury which determined the defendant's guilt;

(B) before a jury impaneled for the purpose of the hearing if—

(i) the defendant was convicted upon a plea of guilty;

(ii) the defendant was convicted after a trial before the court sitting without a jury;

(iii) the jury which determined the defendant's guilt has been discharged for good cause; or

(iv) after initial imposition of a sentence under this section, redetermination of the sentence under this section is necessary; or

(C) before the court alone, upon the motion of the defendant and with the approval of the Government.

(2) A jury impaneled under paragraph (1)(B) shall consist of 12 members, unless, at any time before the conclusion of the hearing, the parties stipulate with the approval of the court that it shall consist of any number less than 12.

**(j) Proof of aggravating and mitigating factors**

Notwithstanding rule 32(c) of the Federal Rules of Criminal Procedure, when a defendant is found guilty of or pleads guilty to an offense under subsection (e) of this section, no presentence report shall be prepared. In the sentencing hearing, information may be presented as to matters relating to any of the aggravating or mitigating factors set forth in subsections (m) and (n) of this section, or any other mitigating factor or any other aggravating factor for which notice has been provided under subsection (h)(1)(B) of this section. Where information is presented relating to any of the aggravating factors set forth in subsection (n) of this section, information may be presented relating to any other aggravating factor for which notice has been provided under subsection (h)(1)(B) of this section. Information presented may include the trial transcript and exhibits if the hearing is held before a jury or judge not present during the trial, or at the trial judge's discretion. Any other information relevant to such mitigating or aggravating factors may be presented by either the Government or the defendant, regard-

[1] So in original. Probably should be paragraph ''(1)(B),''.

[2] So in original. Section does not contain a subsec. (f), see 1988 Amendment note below.

less of its admissibility under the rules governing admission of evidence at criminal trials, except that information may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. The Government and the defendant shall be permitted to rebut any information received at the hearing and shall be given fair opportunity to present argument as to the adequacy of the information to establish the existence of any of the aggravating or mitigating factors and as to appropriateness in that case of imposing a sentence of death. The Government shall open the argument. The defendant shall be permitted to reply. The Government shall then be permitted to reply in rebuttal. The burden of establishing the existence of any aggravating factor is on the Government, and is not satisfied unless established beyond a reasonable doubt. The burden of establishing the existence of any mitigating factor is on the defendant, and is not satisfied unless established by a preponderance of the evidence.

**(k) Return of findings**

The jury, or if there is no jury, the court, shall consider all the information received during the hearing. It shall return special findings identifying any aggravating factors set forth in subsection (n) of this section, found to exist. If one of the aggravating factors set forth in subsection (n)(1) of this section and another of the aggravating factors set forth in paragraphs (2) through (12) of subsection (n) of this section is found to exist, a special finding identifying any other aggravating factor for which notice has been provided under subsection (h)(1)(B) of this section, may be returned. A finding with respect to a mitigating factor may be made by one or more of the members of the jury, and any member of the jury who finds the existence of a mitigating factor may consider such a factor established for purposes of this subsection, regardless of the number of jurors who concur that the factor has been established. A finding with respect to any aggravating factor must be unanimous. If an aggravating factor set forth in subsection (n)(1) of this section is not found to exist or an aggravating factor set forth in subsection (n)(1) of this section is found to exist but no other aggravating factor set forth in subsection (n) of this section is found to exist, the court shall impose a sentence, other than death, authorized by law. If an aggravating factor set forth in subsection (n)(1) of this section and one or more of the other aggravating factors set forth in subsection (n) of this section are found to exist, the jury, or if there is no jury, the court, shall then consider whether the aggravating factors found to exist sufficiently outweigh any mitigating factor or factors found to exist, or in the absence of mitigating factors, whether the aggravating factors are themselves sufficient to justify a sentence of death. Based upon this consideration, the jury by unanimous vote, or if there is no jury, the court, shall recommend that a sentence of death shall be imposed rather than a sentence of life imprisonment without possibility of release or some other lesser sentence. The jury or the court, regardless of its findings with respect to aggravating and mitigating factors, is never required to impose a death sentence and the jury shall be so instructed.

**(*l*) Imposition of sentence**

Upon the recommendation that the sentence of death be imposed, the court shall sentence the defendant to death. Otherwise the court shall impose a sentence, other than death, authorized by law. A sentence of death shall not be carried out upon a person who is under 18 years of age at the time the crime was committed. A sentence of death shall not be carried out upon a person who is mentally retarded. A sentence of death shall not be carried out upon a person who, as a result of mental disability—

(1) cannot understand the nature of the pending proceedings, what such person was tried for, the reason for the punishment, or the nature of the punishment; or

(2) lacks the capacity to recognize or understand facts which would make the punishment unjust or unlawful, or lacks the ability to convey such information to counsel or to the court.

**(m) Mitigating factors**

In determining whether a sentence of death is to be imposed on a defendant, the finder of fact shall consider mitigating factors, including the following:

(1) The defendant's capacity to appreciate the wrongfulness of the defendant's conduct or to conform conduct to the requirements of law was significantly impaired, regardless of whether the capacity was so impaired as to constitute a defense to the charge.

(2) The defendant was under unusual and substantial duress, regardless of whether the duress was of such a degree as to constitute a defense to the charge.

(3) The defendant is punishable as a principal (as defined in section 2 of title 18) in the offense, which was committed by another, but the defendant's participation was relatively minor, regardless of whether the participation was so minor as to constitute a defense to the charge.

(4) The defendant could not reasonably have foreseen that the defendant's conduct in the course of the commission of murder, or other offense resulting in death for which the defendant was convicted, would cause, or would create a grave risk of causing, death to any person.

(5) The defendant was youthful, although not under the age of 18.

(6) The defendant did not have a significant prior criminal record.

(7) The defendant committed the offense under severe mental or emotional disturbance.

(8) Another defendant or defendants, equally culpable in the crime, will not be punished by death.

(9) The victim consented to the criminal conduct that resulted in the victim's death.

(10) That other factors in the defendant's background or character mitigate against imposition of the death sentence.

**(n) Aggravating factors for homicide**

If the defendant is found guilty of or pleads guilty to an offense under subsection (e) of this

section, the following aggravating factors are the only aggravating factors that shall be considered, unless notice of additional aggravating factors is provided under subsection (h)(1)(B) of this section:

(1) The defendant—

(A) intentionally killed the victim;

(B) intentionally inflicted serious bodily injury which resulted in the death of the victim;

(C) intentionally engaged in conduct intending that the victim be killed or that lethal force be employed against the victim, which resulted in the death of the victim;

(D) intentionally engaged in conduct which—

(i) the defendant knew would create a grave risk of death to a person, other than one of the participants in the offense; and

(ii) resulted in the death of the victim.

(2) The defendant has been convicted of another Federal offense, or a State offense resulting in the death of a person, for which a sentence of life imprisonment or a sentence of death was authorized by statute.

(3) The defendant has previously been convicted of two or more State or Federal offenses punishable by a term of imprisonment of more than one year, committed on different occasions, involving the infliction of, or attempted infliction of, serious bodily injury upon another person.

(4) The defendant has previously been convicted of two or more State or Federal offenses punishable by a term of imprisonment of more than one year, committed on different occasions, involving the distribution of a controlled substance.

(5) In the commission of the offense or in escaping apprehension for a violation of subsection (e) of this section, the defendant knowingly created a grave risk of death to one or more persons in addition to the victims of the offense.

(6) The defendant procured the commission of the offense by payment, or promise of payment, of anything of pecuniary value.

(7) The defendant committed the offense as consideration for the receipt, or in the expectation of the receipt, of anything of pecuniary value.

(8) The defendant committed the offense after substantial planning and premeditation.

(9) The victim was particularly vulnerable due to old age, youth, or infirmity.

(10) The defendant had previously been convicted of violating this subchapter or subchapter II of this chapter for which a sentence of five or more years may be imposed or had previously been convicted of engaging in a continuing criminal enterprise.

(11) The violation of this subchapter in relation to which the conduct described in subsection (e) of this section occurred was a violation of section 859 of this title.

(12) The defendant committed the offense in an especially heinous, cruel, or depraved manner in that it involved torture or serious physical abuse to the victim.

**(*o*) Right of defendant to justice without discrimination**

(1) In any hearing held before a jury under this section, the court shall instruct the jury that in its consideration of whether the sentence of death is justified it shall not consider the race, color, religious beliefs, national origin, or sex of the defendant or the victim, and that the jury is not to recommend a sentence of death unless it has concluded that it would recommend a sentence of death for the crime in question no matter what the race, color, religious beliefs, national origin, or sex of the defendant, or the victim, may be. The jury shall return to the court a certificate signed by each juror that consideration of the race, color, religious beliefs, national origin, or sex of the defendant or the victim was not involved in reaching his or her individual decision, and that the individual juror would have made the same recommendation regarding a sentence for the crime in question no matter what the race, color, religious beliefs, national origin, or sex of the defendant, or the victim, may be.

(2) Not later than one year from November 18, 1988, the Comptroller General shall conduct a study of the various procedures used by the several States for determining whether or not to impose the death penalty in particular cases, and shall report to the Congress on whether or not any or all of the various procedures create a significant risk that the race of a defendant, or the race of a victim against whom a crime was committed, influence the likelihood that defendants in those States will be sentenced to death. In conducting the study required by this paragraph, the General Accounting Office shall—

(A) use ordinary methods of statistical analysis, including methods comparable to those ruled admissible by the courts in race discrimination cases under title VII of the Civil Rights Act of 1964 [42 U.S.C. 2000e et seq.];

(B) study only crimes occurring after January 1, 1976; and

(C) determine what, if any, other factors, including any relation between any aggravating or mitigating factors and the race of the victim or the defendant, may account for any evidence that the race of the defendant, or the race of the victim, influences the likelihood that defendants will be sentenced to death. In addition, the General Accounting Office shall examine separately and include in the report, death penalty cases involving crimes similar to those covered under this section.

**(p) Sentencing in capital cases in which death penalty is not sought or imposed**

If a person is convicted for an offense under subsection (e) of this section and the court does not impose the penalty of death, the court may impose a sentence of life imprisonment without the possibility of parole.

**(q) Appeal in capital cases; counsel for financially unable defendants**

(1) In any case in which the sentence of death is imposed under this section, the sentence of death shall be subject to review by the court of appeals upon appeal by the defendant. Notice of

appeal must be filed within the time prescribed for appeal of judgment in section 2107 of title 28. An appeal under this section may be consolidated with an appeal of the judgment of conviction. Such review shall have priority over all other cases.

(2) On review of the sentence, the court of appeals shall consider the record, the evidence submitted during the trial, the information submitted during the sentencing hearing, the procedures employed in the sentencing hearing, and the special findings returned under this section.

(3) The court shall affirm the sentence if it determines that—

(A) the sentence of death was not imposed under the influence of passion, prejudice, or any other arbitrary factor; and

(B) the information supports the special finding of the existence of every aggravating factor upon which the sentence was based, together with, or the failure to find, any mitigating factors as set forth or allowed in this section.

In all other cases the court shall remand the case for reconsideration under this section. The court of appeals shall state in writing the reasons for its disposition of the review of the sentence.

(4)(A) Notwithstanding any other provision of law to the contrary, in every criminal action in which a defendant is charged with a crime which may be punishable by death, a defendant who is or becomes financially unable to obtain adequate representation or investigative, expert, or other reasonably necessary services at any time either—

(i) before judgment; or

(ii) after the entry of a judgment imposing a sentence of death but before the execution of that judgment;

shall be entitled to the appointment of one or more attorneys and the furnishing of such other services in accordance with paragraphs (5), (6), (7), (8), and (9).

(B) In any post conviction proceeding under section 2254 or 2255 of title 28 seeking to vacate or set aside a death sentence, any defendant who is or becomes financially unable to obtain adequate representation or investigative, expert, or other reasonably necessary services shall be entitled to the appointment of one or more attorneys and the furnishing of such other services in accordance with paragraphs (5), (6), (7), (8), and (9).

(5) If the appointment is made before judgment, at least one attorney so appointed must have been admitted to practice in the court in which the prosecution is to be tried for not less than five years, and must have had not less than three years experience in the actual trial of felony prosecutions in that court.

(6) If the appointment is made after judgment, at least one attorney so appointed must have been admitted to practice in the court of appeals for not less than five years, and must have had not less than three years experience in the handling of appeals in that court in felony cases.

(7) With respect to paragraphs (5) and (6), the court, for good cause, may appoint another attorney whose background, knowledge, or experience would otherwise enable him or her to properly represent the defendant, with due consideration to the seriousness of the possible penalty and to the unique and complex nature of the litigation.

(8) Unless replaced by similarly qualified counsel upon the attorney's own motion or upon motion of the defendant, each attorney so appointed shall represent the defendant throughout every subsequent stage of available judicial proceedings, including pretrial proceedings, trial, sentencing, motions for new trial, appeals, applications for writ of certiorari to the Supreme Court of the United States, and all available post-conviction process, together with applications for stays of execution and other appropriate motions and procedures, and shall also represent the defendant in such competency proceedings and proceedings for executive or other clemency as may be available to the defendant.

(9) Upon a finding in ex parte proceedings that investigative, expert or other services are reasonably necessary for the representation of the defendant, whether in connection with issues relating to guilt or sentence, the court shall authorize the defendant's attorneys to obtain such services on behalf of the defendant and shall order the payment of fees and expenses therefore, under paragraph (10). Upon a finding that timely procurement of such services could not practicably await prior authorization, the court may authorize the provision of and payment for such services nunc pro tunc.

(10) Notwithstanding the rates and maximum limits generally applicable to criminal cases and any other provision of law to the contrary, the court shall fix the compensation to be paid to attorneys appointed under this subsection and the fees and expenses to be paid for investigative, expert, and other reasonably necessary services authorized under paragraph (9), at such rates or amounts as the court determines to be reasonably necessary to carry out the requirements of paragraphs (4) through (9).

**(r) Refusal to participate by State and Federal correctional employees**

No employee of any State department of corrections or the Federal Bureau of Prisons and no employee providing services to that department or bureau under contract shall be required, as a condition of that employment, or contractual obligation to be in attendance at or to participate in any execution carried out under this section if such participation is contrary to the moral or religious convictions of the employee. For purposes of this subsection, the term ''participation in executions'' includes personal preparation of the condemned individual and the apparatus used for execution and supervision of the activities of other personnel in carrying out such activities.

(Pub. L. 91–513, title II, § 408, Oct. 27, 1970, 84 Stat. 1265; Pub. L. 98–473, title II, §§ 224(b), formerly § 224(c), 305, Oct. 12, 1984, 98 Stat. 2030, 2050; Pub. L. 99–570, title I, §§ 1005(b)(2), 1252, 1253, Oct. 27, 1986, 100 Stat. 3207–6, 3207–14; Pub. L. 100–690, title VI, § 6481, title VII, § 7001, Nov. 18, 1988, 102 Stat. 4382, 4387; Pub. L. 103–322, title XXXIII, §§ 330003(e), 330009(d), 330014, Sept. 13, 1994, 108 Stat. 2141, 2143, 2146.)

REFERENCES IN TEXT

Act of July 15, 1932 (D.C. Code, secs. 24–203—24–207), referred to in subsec. (d), is act July 15, 1932, ch. 492, 47 Stat. 696, as amended, which appears in sections 24–203 to 24–209 of Title 24, Prisoners and Their Treatment, and section 22–2601 of Title 22, Criminal Offenses, of the District of Columbia Code.

The Federal Rules of Criminal Procedure, referred to in subsec. (j), are set out in the Appendix to Title 18, Crimes and Criminal Procedure.

The Civil Rights Act of 1964, referred to in subsec. (*o*)(2)(A), is Pub. L. 88–352, July 2, 1964, 78 Stat. 241, as amended. Title VII of the Civil Rights Act of 1964 is classified generally to subchapter VI (§ 2000e et seq.) of chapter 21 of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 2000a of Title 42 and Tables.

AMENDMENTS

1994—Subsec. (b)(2)(A). Pub. L. 103–322, § 330003(e), substituted ''subsection (c)(1) of this section'' for ''subsection (d)(1) of this section''.

Subsec. (n)(11). Pub. L. 103–322, § 330014, made technical amendment to reference to section 859 of this title to correct reference to corresponding section of original act.

Subsec. (q)(8). Pub. L. 103–322, § 330009(d), substituted ''applications for writ'' for ''applications, for writ''.

1988—Subsec. (a). Pub. L. 100–690, § 6481(a), increased minimum term of imprisonment for first violations to 20 from 10 years and for subsequent violations to 30 from 20 years.

Subsecs. (c), (d). Pub. L. 100–690, § 6481(b), redesignated subsecs. (d) and (e) as (c) and (d), respectively.

Subsec. (e). Pub. L. 100–690, § 7001(a)(2), added subsec. (e). Former subsec. (e) redesignated (d).

Pub. L. 100–690, § 7001(a)(1), which directed redesignation of former subsec. (e) as (f), could not be executed because of prior redesignation of former subsec. (e) as (d) by Pub. L. 100–690, § 6481(b), which resulted in there not being a subsec. (f).

Subsecs. (g) to (r). Pub. L. 100–690, § 7001(b), added subsecs. (g) to (r).

1986—Subsec. (a). Pub. L. 99–570, § 1252, substituted ''to a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual,'' for ''to a fine of not more than $100,000,'' and ''to a fine not to exceed the greater of twice the amount authorized in accordance with the provisions of title 18 or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual,'' for ''to a fine of not more than $200,000,''.

Subsecs. (b) to (e). Pub. L. 99–570, § 1253, added subsec. (b) and redesignated former subsecs. (b) and (c) as (d) and (e), respectively, which resulted in there not being a subsec. (c).

1984—Subsec. (a). Pub. L. 98–473, § 305, struck out par. (1) designation, substituted references to section 853 of this title for references to paragraph (2) in two places, and struck out par. (2) which related to forfeitures to the United States by any person convicted under par. (1).

Subsec. (d). Pub. L. 98–473, § 305(b), struck out subsec. (d) relating to jurisdiction of courts of the United States.

Subsec. (e). Pub. L. 98–473, § 224(b), as renumbered by Pub. L. 99–570, § 1005(b)(2), which directed the amendment of subsec. (c) of this section by striking out ''and section 4202 of title 18 of the United States Code'', was executed by striking out that language in subsec. (e) to reflect the probable intent of Congress and the intervening amendment by Pub. L. 99–570, § 1253, which redesignated subsec. (c) as (e). See 1986 Amendment note above.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 224(b) of Pub. L. 98–473 effective Nov. 1, 1987, and applicable only to offenses committed after the taking effect of such amendment, see section 235(a)(1) of Pub. L. 98–473, set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure.

GAO STUDY OF COST OF EXECUTIONS

Section 7002 of title VII of Pub. L. 100–690 provided that:

''(a) STUDY.—No later than three years after the date of the enactment of this Act [Nov. 18, 1988], the Comptroller General shall carry out a study to review the cost of implementing the procedures for imposing and carrying out a death sentence prescribed by this title [see Tables for classification].

''(b) SPECIFIC REQUIREMENT.—Such study shall consider, but not be limited to, information concerning impact on workload of the Federal prosecutors and judiciary and law enforcement necessary to obtain capital sentences and executions under this Act [see Short Title note set out under section 1501 of this title].

''(c) SUBMISSION OF REPORT.—Not later than four years after date of the enactment of this Act [Nov. 18, 1988], the Comptroller General shall submit to Congress a report describing the results of the study.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 853 of this title; title 18 sections 36, 1956, 3553, 3559, 3591, 3592.

## § 849. Transportation safety offenses

### (a) Definitions

In this section—

''safety rest area'' means a roadside facility with parking facilities for the rest or other needs of motorists.

''truck stop'' means a facility (including any parking lot appurtenant thereto) that—

(A) has the capacity to provide fuel or service, or both, to any commercial motor vehicle (as defined in section 31301 of title 49), operating in commerce (as defined in that section); and

(B) is located within 2,500 feet of the National System of Interstate and Defense Highways or the Federal-Aid Primary System.

### (b) First offense

A person who violates section 841(a)(1) of this title or section 856 of this title by distributing or possessing with intent to distribute a controlled substance in or on, or within 1,000 feet of, a truck stop or safety rest area is (except as provided in subsection (b)[1] of this section) subject to—

(1) twice the maximum punishment authorized by section 841(b) of this title; and

(2) twice any term of supervised release authorized by section 841(b) of this title for a first offense.

### (c) Subsequent offense

A person who violates section 841(a)(1) of this title or section 856 of this title by distributing or possessing with intent to distribute a controlled substance in or on, or within 1,000 feet of, a truck stop or a safety rest area after a prior conviction or convictions under subsection (a)[2] of this section have become final is subject to—

(1) 3 times the maximum punishment authorized by section 841(b) of this title; and

[1] So in original. Probably should be subsection ''(c)''.

[2] So in original. Probably should be subsection ''(b)''.

(2) 3 times any term of supervised release authorized by section 841(b) of this title for a first offense.

(Pub. L. 91–513, title II, § 409, as added Pub. L. 103–322, title XVIII, § 180201(b)(1), Sept. 13, 1994, 108 Stat. 2046.)

PRIOR PROVISIONS

A prior section 849, Pub. L. 91–513, title II, § 409, Oct. 27, 1970, 84 Stat. 1266; Pub. L. 99–514, § 2, Oct. 22, 1986, 100 Stat. 2095, related to dangerous special drug offender sentencing, prior to repeal by Pub. L. 98–473, title II, §§ 219(a), 235(a)(1), Oct. 12, 1984, 98 Stat. 2027, 2031, eff. Nov. 1, 1987, and applicable only to offenses committed after the taking effect of such repeal.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 841 of this title.

### § 850. Information for sentencing

Except as otherwise provided in this subchapter or section 242a(a) of title 42, no limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence under this subchapter or subchapter II of this chapter.

(Pub. L. 91–513, title II, § 410, Oct. 27, 1970, 84 Stat. 1269.)

### § 851. Proceedings to establish prior convictions

#### (a) Information filed by United States Attorney

(1) No person who stands convicted of an offense under this part shall be sentenced to increased punishment by reason of one or more prior convictions, unless before trial, or before entry of a plea of guilty, the United States attorney files an information with the court (and serves a copy of such information on the person or counsel for the person) stating in writing the previous convictions to be relied upon. Upon a showing by the United States attorney that facts regarding prior convictions could not with due diligence be obtained prior to trial or before entry of a plea of guilty, the court may postpone the trial or the taking of the plea of guilty for a reasonable period for the purpose of obtaining such facts. Clerical mistakes in the information may be amended at any time prior to the pronouncement of sentence.

(2) An information may not be filed under this section if the increased punishment which may be imposed is imprisonment for a term in excess of three years unless the person either waived or was afforded prosecution by indictment for the offense for which such increased punishment may be imposed.

#### (b) Affirmation or denial of previous conviction

If the United States attorney files an information under this section, the court shall after conviction but before pronouncement of sentence inquire of the person with respect to whom the information was filed whether he affirms or denies that he has been previously convicted as alleged in the information, and shall inform him that any challenge to a prior conviction which is not made before sentence is imposed may not thereafter be raised to attack the sentence.

#### (c) Denial; written response; hearing

(1) If the person denies any allegation of the information of prior conviction, or claims that any conviction alleged is invalid, he shall file a written response to the information. A copy of the response shall be served upon the United States attorney. The court shall hold a hearing to determine any issues raised by the response which would except the person from increased punishment. The failure of the United States attorney to include in the information the complete criminal record of the person or any facts in addition to the convictions to be relied upon shall not constitute grounds for invalidating the notice given in the information required by subsection (a)(1) of this section. The hearing shall be before the court without a jury and either party may introduce evidence. Except as otherwise provided in paragraph (2) of this subsection, the United States attorney shall have the burden of proof beyond a reasonable doubt on any issue of fact. At the request of either party, the court shall enter findings of fact and conclusions of law.

(2) A person claiming that a conviction alleged in the information was obtained in violation of the Constitution of the United States shall set forth his claim, and the factual basis therefor, with particularity in his response to the information. The person shall have the burden of proof by a preponderance of the evidence on any issue of fact raised by the response. Any challenge to a prior conviction, not raised by response to the information before an increased sentence is imposed in reliance thereon, shall be waived unless good cause be shown for failure to make a timely challenge.

#### (d) Imposition of sentence

(1) If the person files no response to the information, or if the court determines, after hearing, that the person is subject to increased punishment by reason of prior convictions, the court shall proceed to impose sentence upon him as provided by this part.

(2) If the court determines that the person has not been convicted as alleged in the information, that a conviction alleged in the information is invalid, or that the person is otherwise not subject to an increased sentence as a matter of law, the court shall, at the request of the United States attorney, postpone sentence to allow an appeal from that determination. If no such request is made, the court shall impose sentence as provided by this part. The person may appeal from an order postponing sentence as if sentence had been pronounced and a final judgment of conviction entered.

#### (e) Statute of limitations

No person who stands convicted of an offense under this part may challenge the validity of any prior conviction alleged under this section which occurred more than five years before the date of the information alleging such prior conviction.

(Pub. L. 91–513, title II, § 411, Oct. 27, 1970, 84 Stat. 1269.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 962 of this title; title 18 section 3559.

### § 852. Application of treaties and other international agreements

Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit the provision of treatment, education, or rehabilitation as alternatives to conviction or criminal penalty for offenses involving any drug or other substance subject to control under any such treaty or agreement.

(Pub. L. 91–513, title II, § 412, as added Pub. L. 95–633, title I, § 107(a), Nov. 10, 1978, 92 Stat. 3773.)

EFFECTIVE DATE

Section effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as a note under section 801a of this title.

### § 853. Criminal forfeitures

#### (a) Property subject to criminal forfeiture

Any person convicted of a violation of this subchapter or subchapter II of this chapter punishable by imprisonment for more than one year shall forfeit to the United States, irrespective of any provision of State law—

(1) any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of such violation;

(2) any of the person's property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, such violation; and

(3) in the case of a person convicted of engaging in a continuing criminal enterprise in violation of section 848 of this title, the person shall forfeit, in addition to any property described in paragraph (1) or (2), any of his interest in, claims against, and property or contractual rights affording a source of control over, the continuing criminal enterprise.

The court, in imposing sentence on such person, shall order, in addition to any other sentence imposed pursuant to this subchapter or subchapter II of this chapter, that the person forfeit to the United States all property described in this subsection. In lieu of a fine otherwise authorized by this part, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

#### (b) Meaning of term "property"

Property subject to criminal forfeiture under this section includes—

(1) real property, including things growing on, affixed to, and found in land; and

(2) tangible and intangible personal property, including rights, privileges, interests, claims, and securities.

#### (c) Third party transfers

All right, title, and interest in property described in subsection (a) of this section vests in the United States upon the commission of the act giving rise to forfeiture under this section. Any such property that is subsequently transferred to a person other than the defendant may be the subject of a special verdict of forfeiture and thereafter shall be ordered forfeited to the United States, unless the transferee establishes in a hearing pursuant to subsection (n) of this section that he is a bona fide purchaser for value of such property who at the time of purchase was reasonably without cause to believe that the property was subject to forfeiture under this section.

#### (d) Rebuttable presumption

There is a rebuttable presumption at trial that any property of a person convicted of a felony under this subchapter or subchapter II of this chapter is subject to forfeiture under this section if the United States establishes by a preponderance of the evidence that—

(1) such property was acquired by such person during the period of the violation of this subchapter or subchapter II of this chapter or within a reasonable time after such period; and

(2) there was no likely source for such property other than the violation of this subchapter or subchapter II of this chapter.

#### (e) Protective orders

(1) Upon application of the United States, the court may enter a restraining order or injunction, require the execution of a satisfactory performance bond, or take any other action to preserve the availability of property described in subsection (a) of this section for forfeiture under this section—

(A) upon the filing of an indictment or information charging a violation of this subchapter or subchapter II of this chapter for which criminal forfeiture may be ordered under this section and alleging that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section; or

(B) prior to the filing of such an indictment or information, if, after notice to persons appearing to have an interest in the property and opportunity for a hearing, the court determines that—

(i) there is a substantial probability that the United States will prevail on the issue of forfeiture and that failure to enter the order will result in the property being destroyed, removed from the jurisdiction of the court, or otherwise made unavailable for forfeiture; and

(ii) the need to preserve the availability of the property through the entry of the requested order outweighs the hardship on any party against whom the order is to be entered:

*Provided, however*, That an order entered pursuant to subparagraph (B) shall be effective for not more than ninety days, unless extended by the court for good cause shown or unless an indictment or information described in subparagraph (A) has been filed.

(2) A temporary restraining order under this subsection may be entered upon application of

the United States without notice or opportunity for a hearing when an information or indictment has not yet been filed with respect to the property, if the United States demonstrates that there is probable cause to believe that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section and that provision of notice will jeopardize the availability of the property for forfeiture. Such a temporary order shall expire not more than ten days after the date on which it is entered, unless extended for good cause shown or unless the party against whom it is entered consents to an extension for a longer period. A hearing requested concerning an order entered under this paragraph shall be held at the earliest possible time and prior to the expiration of the temporary order.

(3) The court may receive and consider, at a hearing held pursuant to this subsection, evidence and information that would be inadmissible under the Federal Rules of Evidence.

**(f) Warrant of seizure**

The Government may request the issuance of a warrant authorizing the seizure of property subject to forfeiture under this section in the same manner as provided for a search warrant. If the court determines that there is probable cause to believe that the property to be seized would, in the event of conviction, be subject to forfeiture and that an order under subsection (e) of this section may not be sufficient to assure the availability of the property for forfeiture, the court shall issue a warrant authorizing the seizure of such property.

**(g) Execution**

Upon entry of an order of forfeiture under this section, the court shall authorize the Attorney General to seize all property ordered forfeited upon such terms and conditions as the court shall deem proper. Following entry of an order declaring the property forfeited, the court may, upon application of the United States, enter such appropriate restraining orders or injunctions, require the execution of satisfactory performance bonds, appoint receivers, conservators, appraisers, accountants, or trustees, or take any other action to protect the interest of the United States in the property ordered forfeited. Any income accruing to or derived from property ordered forfeited under this section may be used to offset ordinary and necessary expenses to the property which are required by law, or which are necessary to protect the interests of the United States or third parties.

**(h) Disposition of property**

Following the seizure of property ordered forfeited under this section, the Attorney General shall direct the disposition of the property by sale or any other commercially feasible means, making due provision for the rights of any innocent persons. Any property right or interest not exercisable by, or transferable for value to, the United States shall expire and shall not revert to the defendant, nor shall the defendant or any person acting in concert with him or on his behalf be eligible to purchase forfeited property at any sale held by the United States. Upon application of a person, other than the defendant or a person acting in concert with him or on his behalf, the court may restrain or stay the sale or disposition of the property pending the conclusion of any appeal of the criminal case giving rise to the forfeiture, if the applicant demonstrates that proceeding with the sale or disposition of the property will result in irreparable injury, harm, or loss to him.

**(i) Authority of the Attorney General**

With respect to property ordered forfeited under this section, the Attorney General is authorized to—

(1) grant petitions for mitigation or remission of forfeiture, restore forfeited property to victims of a violation of this subchapter, or take any other action to protect the rights of innocent persons which is in the interest of justice and which is not inconsistent with the provisions of this section;

(2) compromise claims arising under this section;

(3) award compensation to persons providing information resulting in a forfeiture under this section;

(4) direct the disposition by the United States, in accordance with the provisions of section 881(e) of this title, of all property ordered forfeited under this section by public sale or any other commercially feasible means, making due provision for the rights of innocent persons; and

(5) take appropriate measures necessary to safeguard and maintain property ordered forfeited under this section pending its disposition.

**(j) Applicability of civil forfeiture provisions**

Except to the extent that they are inconsistent with the provisions of this section, the provisions of section 881(d) of this title shall apply to a criminal forfeiture under this section.

**(k) Bar on intervention**

Except as provided in subsection (n) of this section, no party claiming an interest in property subject to forfeiture under this section may—

(1) intervene in a trial or appeal of a criminal case involving the forfeiture of such property under this section; or

(2) commence an action at law or equity against the United States concerning the validity of his alleged interest in the property subsequent to the filing of an indictment or information alleging that the property is subject to forfeiture under this section.

**(*l*) Jurisdiction to enter orders**

The district courts of the United States shall have jurisdiction to enter orders as provided in this section without regard to the location of any property which may be subject to forfeiture under this section or which has been ordered forfeited under this section.

**(m) Depositions**

In order to facilitate the identification and location of property declared forfeited and to facilitate the disposition of petitions for remission or mitigation of forfeiture, after the entry of an order declaring property forfeited to the United States, the court may, upon application of the

United States, order that the testimony of any witness relating to the property forfeited be taken by deposition and that any designated book, paper, document, record, recording, or other material not privileged be produced at the same time and place, in the same manner as provided for the taking of depositions under Rule 15 of the Federal Rules of Criminal Procedure.

**(n) Third party interests**

(1) Following the entry of an order of forfeiture under this section, the United States shall publish notice of the order and of its intent to dispose of the property in such manner as the Attorney General may direct. The Government may also, to the extent practicable, provide direct written notice to any person known to have alleged an interest in the property that is the subject of the order of forfeiture as a substitute for published notice as to those persons so notified.

(2) Any person, other than the defendant, asserting a legal interest in property which has been ordered forfeited to the United States pursuant to this section may, within thirty days of the final publication of notice or his receipt of notice under paragraph (1), whichever is earlier, petition the court for a hearing to adjudicate the validity of his alleged interest in the property. The hearing shall be held before the court alone, without a jury.

(3) The petition shall be signed by the petitioner under penalty of perjury and shall set forth the nature and extent of the petitioner's right, title, or interest in the property, the time and circumstances of the petitioner's acquisition of the right, title, or interest in the property, any additional facts supporting the petitioner's claim, and the relief sought.

(4) The hearing on the petition shall, to the extent practicable and consistent with the interests of justice, be held within thirty days of the filing of the petition. The court may consolidate the hearing on the petition with a hearing on any other petition filed by a person other than the defendant under this subsection.

(5) At the hearing, the petitioner may testify and present evidence and witnesses on his own behalf, and cross-examine witnesses who appear at the hearing. The United States may present evidence and witnesses in rebuttal and in defense of its claim to the property and cross-examine witnesses who appear at the hearing. In addition to testimony and evidence presented at the hearing, the court shall consider the relevant portions of the record of the criminal case which resulted in the order of forfeiture.

(6) If, after the hearing, the court determines that the petitioner has established by a preponderance of the evidence that—

(A) the petitioner has a legal right, title, or interest in the property, and such right, title, or interest renders the order of forfeiture invalid in whole or in part because the right, title, or interest was vested in the petitioner rather than the defendant or was superior to any right, title, or interest of the defendant at the time of the commission of the acts which gave rise to the forfeiture of the property under this section; or

(B) the petitioner is a bona fide purchaser for value of the right, title, or interest in the property and was at the time of purchase reasonably without cause to believe that the property was subject to forfeiture under this section;

the court shall amend the order of forfeiture in accordance with its determination.

(7) Following the court's disposition of all petitions filed under this subsection, or if no such petitions are filed following the expiration of the period provided in paragraph (2) for the filing of such petitions, the United States shall have clear title to property that is the subject of the order of forfeiture and may warrant good title to any subsequent purchaser or transferee.

**(*o*) Construction**

The provisions of this section shall be liberally construed to effectuate its remedial purposes.

**(p) Forfeiture of substitute property**

If any of the property described in subsection (a) of this section, as a result of any act or omission of the defendant—

(1) cannot be located upon the exercise of due diligence;

(2) has been transferred or sold to, or deposited with, a third party;

(3) has been placed beyond the jurisdiction of the court;

(4) has been substantially diminished in value; or

(5) has been commingled with other property which cannot be divided without difficulty;

the court shall order the forfeiture of any other property of the defendant up to the value of any property described in paragraphs (1) through (5).

(Pub. L. 91–513, title II, § 413, as added and amended Pub. L. 98–473, title II, §§ 303, 2301(d)–(f), Oct. 12, 1984, 98 Stat. 2044, 2192, 2193; Pub. L. 99–570, title I, §§ 1153(b), 1864, Oct. 27, 1986, 100 Stat. 3207–13, 3207–54.)

REFERENCES IN TEXT

The Federal Rules of Evidence, referred to in subsec. (e)(3), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

The Federal Rules of Criminal Procedure, referred to in subsec. (m), are set out in the Appendix to Title 18, Crimes and Criminal Procedure.

AMENDMENTS

1986—Subsec. (c). Pub. L. 99–570, § 1864(1), substituted "subsection (n)" for "subsection (*o*)".

Subsec. (f). Pub. L. 99–570, § 1864(2), substituted "subsection (e)" for "subsection (f)".

Subsec. (i)(1). Pub. L. 99–570, § 1864(3), substituted "this subchapter" for "this chapter".

Subsec. (k). Pub. L. 99–570, § 1864(1), (4), which directed the substitution of "subsection (n)" for "subsection (*o*)" in "the second subsection (h)", and directed the redesignation of "the second subsection (h)" as subsection (k), were executed to this subsection because the "second subsection (h)" had been editorially redesignated subsec. (k) to reflect the probable intent of Congress. See 1984 Amendment note below.

Subsec. (p). Pub. L. 99–570, § 1153(b), which directed that "section 413 of title II of the Comprehensive Drug Abuse Prevention and Control Act of 1975" be amended "by redesignating subsection '(p)' as subsection '(q)'" and adding subsec. (p) was executed to this section, which is section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as the probable in-

tent of Congress, by adding a subsec. (p) in view of the prior redesignation of subsec. (p) as (*o*) by Pub. L. 98–473, § 2301(e)(2). See 1984 Amendment note below.

1984—Subsec. (a). Pub. L. 98–473, § 2301(d), inserted ''In lieu of a fine otherwise authorized by this part, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.''

Subsec. (d). Pub. L. 98–473, § 2301(e), struck out subsec. (d) which related to forfeiture of property other than that described in subsec. (a) and the conditions therefor, and redesignated former subsec. (e) as (d).

Subsecs. (e) to (p). Pub. L. 98–473, § 2301(e)(2), which directed that this section be amended by redesignating subsecs. (e), (f), (g), (h), (i), (*l*), (m), (n), (*o*), and (p) as subsecs. (d), (e), (f), (g), (h), (i), (j), (h), (*l*), (m), (n), and (*o*), respectively, was executed by redesignating subsecs. (e) to (p) as (d) to (*o*), respectively, to give effect to the probable intent of Congress.

Subsec. (n)(1). Pub. L. 98–473, § 2301(f), struck out ''for at least seven successive court days'' after ''to dispose of the property''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 333, 848, 970 of this title; title 18 sections 793, 794, 982, 3554; title 33 section 1415.

### § 853a. Transferred

CODIFICATION

Section, Pub. L. 100–690, title V, § 5301, Nov. 18, 1988, 102 Stat. 4310, which related to denial of Federal benefits to drug traffickers and possessors, was renumbered section 421 of the Controlled Substances Act by Pub. L. 101–647, title X, § 1002(d)(1), Nov. 29, 1990, 104 Stat. 4827, and is classified to section 862 of this title.

### § 854. Investment of illicit drug profits

#### (a) Prohibition

It shall be unlawful for any person who has received any income derived, directly or indirectly, from a violation of this subchapter or subchapter II of this chapter punishable by imprisonment for more than one year in which such person has participated as a principal within the meaning of section 2 of title 18, to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect interstate or foreign commerce. A purchase of securities on the open market for purposes of investment, and without the intention of controlling or participating in the control of the issuer, or of assisting another to do so, shall not be unlawful under this section if the securities of the issuer held by the purchaser, the members of his immediate family, and his or their accomplices in any violation of this subchapter or subchapter II of this chapter after such purchase do not amount in the aggregate to 1 per centum of the outstanding securities of any one class, and do not confer, either in law or in fact, the power to elect one or more directors of the issuer.

#### (b) Penalty

Whoever violates this section shall be fined not more than $50,000 or imprisoned not more than ten years, or both.

#### (c) "Enterprise" defined

As used in this section, the term ''enterprise'' includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.

#### (d) Construction

The provisions of this section shall be liberally construed to effectuate its remedial purposes.

(Pub. L. 91–513, title II, § 414, as added Pub. L. 98–473, title II, § 303, Oct. 12, 1984, 98 Stat. 2049.)

### § 855. Alternative fine

In lieu of a fine otherwise authorized by this part, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

(Pub. L. 91–513, title II, § 415, as added Pub. L. 98–473, title II, § 2302, Oct. 12, 1984, 98 Stat. 2193.)

### § 856. Establishment of manufacturing operations

(a) Except as authorized by this subchapter, it shall be unlawful to—

(1) knowingly open or maintain any place for the purpose of manufacturing, distributing, or using any controlled substance;

(2) manage or control any building, room, or enclosure, either as an owner, lessee, agent, employee, or mortgagee, and knowingly and intentionally rent, lease, or make available for use, with or without compensation, the building, room, or enclosure for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.

(b) Any person who violates subsection (a) of this section shall be sentenced to a term of imprisonment of not more than 20 years or a fine of not more than $500,000, or both, or a fine of $2,000,000 for a person other than an individual.

(Pub. L. 91–513, title II, § 416, as added Pub. L. 99–570, title I, § 1841(a), Oct. 27, 1986, 100 Stat. 3207–52.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 849, 860 of this title.

### § 857. Repealed. Pub. L. 101–647, title XXIV, § 2401(d), Nov. 29, 1990, 104 Stat. 4859

Section, Pub. L. 99–570, title I, § 1822, Oct. 27, 1986, 100 Stat. 3207–51; Pub. L. 100–690, title VI, § 6485, Nov. 18, 1988, 102 Stat. 4384; Pub. L. 101–647, title XXIV, § 2401(b), Nov. 29, 1990, 104 Stat. 4859, related to interstate and foreign sale and transportation of drug paraphernalia.

Subsec. (a), which related to unlawful acts, was repealed.

Subsecs. (b) to (f) were redesignated as subsecs. (b) to (f) of section 422 of the Controlled Substances Act by section 2401(b) of Pub. L. 101–647 and transferred to section 863(b) to (f) of this title.

EFFECTIVE DATE

Section 1823 of Pub. L. 99–570 which provided that subtitle O (§§ 1821–1823) of title I of Pub. L. 99–570, enacting this section and provisions set out as a note under section 801 of this title, was to become effective 90 days after Oct. 27, 1986, was repealed by Pub. L. 101–647, title XXIV, § 2401(d), Nov. 29, 1990, 104 Stat. 4859.

### § 858. Endangering human life while illegally manufacturing controlled substance

Whoever, while manufacturing a controlled substance in violation of this subchapter, or at-

tempting to do so, or transporting or causing to be transported materials, including chemicals, to do so, creates a substantial risk of harm to human life shall be fined in accordance with title 18 or imprisoned not more than 10 years, or both.

(Pub. L. 91–513, title II, § 417, as added Pub. L. 100–690, title VI, § 6301(a), Nov. 18, 1988, 102 Stat. 4370.)

### § 859. Distribution to persons under age twenty-one

#### (a) First offense

Except as provided in section 860 of this title, any person at least eighteen years of age who violates section 841(a)(1) of this title by distributing a controlled substance to a person under twenty-one years of age is (except as provided in subsection (b) of this section) subject to (1) twice the maximum punishment authorized by section 841(b) of this title, and (2) at least twice any term of supervised release authorized by section 841(b) of this title, for a first offense involving the same controlled substance and schedule. Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a term of imprisonment under this subsection shall be not less than one year. The mandatory minimum sentencing provisions of this subsection shall not apply to offenses involving 5 grams or less of marihuana.

#### (b) Second offense

Except as provided in section 860 of this title, any person at least eighteen years of age who violates section 841(a)(1) of this title by distributing a controlled substance to a person under twenty-one years of age after a prior conviction under subsection (a) of this section (or under section 333(b) of this title as in effect prior to May 1, 1971) has become final, is subject to (1) three times the maximum punishment authorized by section 841(b) of this title, and (2) at least three times any term of supervised release authorized by section 841(b) of this title, for a second or subsequent offense involving the same controlled substance and schedule. Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a term of imprisonment under this subsection shall be not less than one year. Penalties for third and subsequent convictions shall be governed by section 841(b)(1)(A) of this title.

(Pub. L. 91–513, title II, § 418, formerly § 405, Oct. 27, 1970, 84 Stat. 1265; Pub. L. 98–473, title II, §§ 224(b), 503(b)(3), Oct. 12, 1984, 98 Stat. 2030, 2070; Pub. L. 99–570, title I, §§ 1004(a), 1005(b)(1), 1105(a), (b), Oct. 27, 1986, 100 Stat. 3207–6, 3207–11; Pub. L. 100–690, title VI, §§ 6452(b), 6455, 6456, Nov. 18, 1988, 102 Stat. 4371, 4372; renumbered § 418 and amended Pub. L. 101–647, title X, §§ 1002(a), 1003(a), title XXXV, § 3599L, Nov. 29, 1990, 104 Stat. 4827, 4828, 4932.)

CODIFICATION

Section was classified to section 845 of this title prior to renumbering by Pub. L. 101–647.

AMENDMENTS

1990—Subsec. (a). Pub. L. 101–647, § 1003(a)(1), substituted ''subject to (1) twice the maximum punishment authorized by section 841(b) of this title'' for ''punishable by (1) a term of imprisonment, or a fine, or both, up to twice that authorized by section 841(b) of this title''.

Pub. L. 101–647, § 1002(a)(2)(A), substituted ''section 860'' for ''section 845a''.

Subsec. (b). Pub. L. 101–647, § 3599L, substituted ''has become final'' for ''have become final''.

Pub. L. 101–647, § 1003(a)(2), substituted ''subject to (1) three times the maximum punishment authorized by section 841(b) of this title'' for ''punishable by (1) a term of imprisonment, or a fine, or both, up to three times that authorized by section 841(b) of this title''.

Pub. L. 101–647, § 1002(a)(2)(B), substituted ''section 860'' for ''section 845a''.

1988—Subsec. (a). Pub. L. 100–690, § 6455, inserted at end ''The mandatory minimum sentencing provisions of this subsection shall not apply to offenses involving 5 grams or less of marihuana.''

Subsec. (b). Pub. L. 100–690, § 6452(b), struck out ''or subsequent'' after ''Second'' in heading, and in text struck out ''or convictions'' after ''a prior conviction'', and inserted at end ''Penalties for third and subsequent convictions shall be governed by section 841(b)(1)(A) of this title.''

Pub. L. 100–690, § 6456, struck out ''The mandatory minimum sentencing provisions of this paragraph shall not apply to offenses involving 5 grams or less of marihuana.''

1986—Subsec. (a). Pub. L. 99–570, § 1105(a), inserted ''Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a term of imprisonment under this subsection shall be not less than one year.''

Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term''.

Subsec. (b). Pub. L. 99–570, § 1105(b), inserted ''Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a term of imprisonment under this subsection shall be not less than one year. The mandatory minimum sentencing provisions of this paragraph shall not apply to offenses involving 5 grams or less of marihuana.''

Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term''.

1984—Subsecs. (a), (b). Pub. L. 98–473, § 503(b)(3), substituted ''Except as provided in section 845a of this title, any'' for ''Any''.

Pub. L. 98–473, § 224(b), which directed amendment of this section effective Nov. 1, 1987 (see section 235(a)(1) of Pub. L. 98–473 set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure) was repealed by Pub. L. 99–570, § 1005(b)(1).

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 1004(a) of Pub. L. 99–570 effective on date of taking effect of section 3583 of Title 18, Crimes and Criminal Procedure (Nov. 1, 1987), see section 1004(b) of Pub. L. 99–570 set out as a note under section 841 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 841 of this title; title 18 section 3592.

### § 860. Distribution or manufacturing in or near schools and colleges

#### (a) Penalty

Any person who violates section 841(a)(1) of this title or section 856 of this title by distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public

housing authority, or within 100 feet of a public or private youth center, public swimming pool, or video arcade facility, is (except as provided in subsection (b) of this section) subject to (1) twice the maximum punishment authorized by section 841(b) of this title; and (2) at least twice any term of supervised release authorized by section 841(b) of this title for a first offense. A fine up to twice that authorized by section 841(b) of this title may be imposed in addition to any term of imprisonment authorized by this subsection. Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a person shall be sentenced under this subsection to a term of imprisonment of not less than one year. The mandatory minimum sentencing provisions of this paragraph shall not apply to offenses involving 5 grams or less of marihuana.

**(b) Second offenders**

Any person who violates section 841(a)(1) of this title or section 856 of this title by distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within one thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private youth center, public swimming pool, or video arcade facility, after a prior conviction under subsection (a) of this section has become final is punishable (1) by the greater of (A) a term of imprisonment of not less than three years and not more than life imprisonment or (B) three times the maximum punishment authorized by section 841(b) of this title for a first offense, and (2) at least three times any term of supervised release authorized by section 841(b) of this title for a first offense. A fine up to three times that authorized by section 841(b) of this title may be imposed in addition to any term of imprisonment authorized by this subsection. Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a person shall be sentenced under this subsection to a term of imprisonment of not less than three years. Penalties for third and subsequent convictions shall be governed by section 841(b)(1)(A) of this title.

**(c) Employing children to distribute drugs near schools or playgrounds**

Notwithstanding any other law, any person at least 21 years of age who knowingly and intentionally—

(1) employs, hires, uses, persuades, induces, entices, or coerces a person under 18 years of age to violate this section; or

(2) employs, hires, uses, persuades, induces, entices, or coerces a person under 18 years of age to assist in avoiding detection or apprehension for any offense under this section by any Federal, State, or local law enforcement official,

is punishable by a term of imprisonment, a fine, or both, up to triple those authorized by section 841 of this title.

**(d) Suspension of sentence; probation; parole**

In the case of any mandatory minimum sentence imposed under this section, imposition or execution of such sentence shall not be suspended and probation shall not be granted. An individual convicted under this section shall not be eligible for parole until the individual has served the mandatory minimum term of imprisonment as provided by this section.

**(e) Definitions**

For the purposes of this section—

(1) The term ''playground'' means any outdoor facility (including any parking lot appurtenant thereto) intended for recreation, open to the public, and with any portion thereof containing three or more separate apparatus intended for the recreation of children including, but not limited to, sliding boards, swingsets, and teeterboards.

(2) The term ''youth center'' means any recreational facility and/or gymnasium (including any parking lot appurtenant thereto), intended primarily for use by persons under 18 years of age, which regularly provides athletic, civic, or cultural activities.

(3) The term ''video arcade facility'' means any facility, legally accessible to persons under 18 years of age, intended primarily for the use of pinball and video machines for amusement containing a minimum of ten pinball and/or video machines.

(4) The term ''swimming pool'' includes any parking lot appurtenant thereto.

(Pub. L. 91–513, title II, § 419, formerly § 405A, as added Pub. L. 98–473, title II, § 503(a), Oct. 12, 1984, 98 Stat. 2069; amended Pub. L. 99–570, title I, §§ 1004(a), 1104, 1105(c), 1841(b), 1866(b), (c), Oct. 27, 1986, 100 Stat. 3207–6, 3207–11, 3207–52, 3207–55; Pub. L. 99–646, § 28, Nov. 10, 1986, 100 Stat. 3598; Pub. L. 100–690, title VI, §§ 6452(b)(1), 6457, 6458, Nov. 18, 1988, 102 Stat. 4371, 4373; renumbered § 419 and amended Pub. L. 101–647, title X, §§ 1002(b), 1003(b), title XII, § 1214, title XV, § 1502, title XXXV, § 3599L, Nov. 29, 1990, 104 Stat. 4827, 4829, 4833, 4836, 4932; Pub. L. 103–322, title XIV, § 140006, title XXXII, § 320107, title XXXIII, § 330009(a), Sept. 13, 1994, 108 Stat. 2032, 2111, 2143.)

CODIFICATION

Section was classified to section 845a of this title prior to renumbering by Pub. L. 101–647.

AMENDMENTS

1994—Subsec. (a). Pub. L. 103–322, § 320107, substituted ''playground, or housing facility owned by a public housing authority, or within'' for ''playground, or within''.

Subsec. (b). Pub. L. 103–322, §§ 320107, 330009(a), substituted ''playground, or housing facility owned by a public housing authority, or within'' for ''playground, or within'' and inserted a period at end of penultimate sentence.

Subsecs. (c) to (e). Pub. L. 103–322, § 140006, added subsec. (c) and redesignated former subsecs. (c) and (d) as (d) and (e), respectively.

1990—Subsec. (a). Pub. L. 101–647, § 1502(1), inserted ''or a playground,'' after ''university,'' and struck out ''playground,'' after ''within 100 feet of a''.

Pub. L. 101–647, § 1214(1)(C), substituted ''a person shall be sentenced under this subsection to a term of imprisonment of not less than one year'' for ''a term of

imprisonment under this subsection shall be not less than one year''.

Pub. L. 101–647, § 1214(1)(B), inserted ''A fine up to twice that authorized by section 841(b) of this title may be imposed in addition to any term of imprisonment authorized by this subsection.''

Pub. L. 101–647, § 1214(1)(A), which directed the amendment of par. (1) by striking out '', or a fine, or both,'' could not be executed because those words did not appear. See note below.

Pub. L. 101–647, § 1003(b)(1), which directed the substitution of ''subject to (1) twice the maximum punishment authorized by section 841(b) of this title'' for ''punishable (1) by a term of imprisonment, or a fine, or both, up to twice that authorized by section 841(b) of this title'', was executed by making the substitution for ''punishable (1) by a term of imprisonment, or fine, or both, up to twice that authorized by section 841(b) of this title'' to reflect the probable intent of Congress.

Subsec. (b). Pub. L. 101–647, § 3599L, substituted ''has become final'' for ''have become final''.

Pub. L. 101–647, § 1502(2), inserted ''or a playground,'' after ''university,'' and struck out ''playground,'' after ''within 100 feet of a''.

Pub. L. 101–647, § 1214(2)(B), inserted after first sentence ''A fine up to three times that authorized by section 841(b) of this title may be imposed in addition to any term of imprisonment authorized by this subsection. Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a person shall be sentenced under this subsection to a term of imprisonment of not less than three years''.

Subsec. (b)(1)(B). Pub. L. 101–647, § 1214(2)(A), which directed the amendment of subpar. (B) by striking '', or a fine up to three times that'' through ''or both'', could not be executed because the language did not appear after execution of the intervening amendment by Pub. L. 101–647, § 1003(b)(2). See below.

Pub. L. 101–647, § 1003(b)(2), substituted ''three times the maximum punishment authorized by section 841(b) of this title for a first offense'' for ''a term of imprisonment of up to three times that authorized by section 841(b) of this title for a first offense, or a fine up to three times that authorized by section 841(b) of this title for a first offense, or both''.

Subsec. (c). Pub. L. 101–647, § 1214(3), inserted ''mandatory minimum'' after ''In the case of any'', struck out ''subsection (b) of'' after ''imposed under'', and substituted ''An individual convicted under this section shall not be eligible for parole until the individual has served the mandatory minimum term of imprisonment as provided by this section'' for ''An individual convicted under subsection (b) of this section shall not be eligible for parole under chapter 311 of title 18 until the individual has served the minimum sentence required by such subsection''.

1988—Subsec. (a). Pub. L. 100–690, §§ 6457, 6458(a), inserted '', possessing with intent to distribute,'' after ''distributing'' and '', or within 100 feet of a playground, public or private youth center, public swimming pool, or video arcade facility,'' after ''university''.

Subsec. (b). Pub. L. 100–690, §§ 6452(b)(1), 6457, 6458(a), inserted '', possessing with intent to distribute,'' after ''distributing'', and '', or within 100 feet of a playground, public or private youth center, public swimming pool, or video arcade facility,'' after ''university'', substituted ''a prior conviction'' for ''a prior conviction or convictions'', and inserted at end ''Penalties for third and subsequent convictions shall be governed by section 841(b)(1)(A) of this title.''

Subsec. (d). Pub. L. 100–690, § 6458(b), added subsec. (d).

1986—Subsec. (a). Pub. L. 99–570, §§ 1104(a), (b), 1105(c), 1841(b)(1), inserted ''or section 856 of this title'' and ''or manufacturing'', substituted ''a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university'' for ''a public or private elementary or secondary school'', struck out ''involving the same controlled substance and schedule'' after ''for a first offense'', and inserted ''Except to the extent a greater minimum sentence is otherwise provided by section 841(b) of this title, a term of imprisonment under this subsection shall be not less than one year. The mandatory minimum sentencing provisions of this paragraph shall not apply to offenses involving 5 grams or less of marihuana.''

Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term''.

Subsec. (b). Pub. L. 99–646 which directed that ''parole'' be inserted after ''(2) at least three times any special'' could not be executed in view of prior amendment by Pub. L. 99–570, § 1104(c) below.

Pub. L. 99–570, § 1166(b), which directed that ''term of supervised release'' be substituted for ''special term'' could not be executed in view of prior amendment by Pub. L. 99–570, § 1104(c) below.

Pub. L. 99–570, §§ 1104(a), 1841(b)(2), inserted reference to section 856 of this title, inserted ''or manufacturing'' after ''distributing'' and substituted ''a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university'' for ''a public or private elementary or secondary school''.

Pub. L. 99–570, § 1104(c), amended cls. (1) and (2) generally. Prior to amendment, cls. (1) and (2) read as follows: ''(1) by a term of imprisonment of not less than three years and not more than life imprisonment and (2) at least three times any special term authorized by section 841(b) of this title for a second or subsequent offense involving the same controlled substance and schedule.''

Subsec. (c). Pub. L. 99–570, § 1866(c), substituted reference to chapter 311 of title 18 for reference to section 4202 of that title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 1004(a) of Pub. L. 99–570 effective on date of taking effect of section 3583 of Title 18, Crimes and Criminal Procedure (Nov. 1, 1987), see section 1004(b) of Pub. L. 99–570 set out as a note under section 841 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 841, 859 of this title; title 18 section 3592.

## § 861. Employment or use of persons under 18 years of age in drug operations

### (a) Unlawful acts

It shall be unlawful for any person at least eighteen years of age to knowingly and intentionally—

(1) employ, hire, use, persuade, induce, entice, or coerce, a person under eighteen years of age to violate any provision of this subchapter or subchapter II of this chapter;

(2) employ, hire, use, persuade, induce, entice, or coerce, a person under eighteen years of age to assist in avoiding detection or apprehension for any offense of this subchapter or subchapter II of this chapter by any Federal, State, or local law enforcement official; or

(3) receive a controlled substance from a person under 18 years of age, other than an immediate family member, in violation of this subchapter or subchapter II of this chapter.

### (b) Penalty for first offense

Any person who violates subsection (a) of this section is subject to twice the maximum punishment otherwise authorized and at least twice any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise pro-

vided, a term of imprisonment under this subsection shall not be less than one year.

**(c) Penalty for subsequent offenses**

Any person who violates subsection (a) of this section after a prior conviction under subsection (a) of this section has become final, is subject to three times the maximum punishment otherwise authorized and at least three times any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise provided, a term of imprisonment under this subsection shall not be less than one year. Penalties for third and subsequent convictions shall be governed by section 841(b)(1)(A) of this title.

**(d) Penalty for providing or distributing controlled substance to underage person**

Any person who violates subsection (a)(1) or (2) of this section[1]

(1) by knowingly providing or distributing a controlled substance or a controlled substance analogue to any person under eighteen years of age; or

(2) if the person employed, hired, or used is fourteen years of age or younger,

shall be subject to a term of imprisonment for not more than five years or a fine of not more than $50,000, or both, in addition to any other punishment authorized by this section.

**(e) Suspension of sentence; probation; parole**

In any case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended and probation shall not be granted. An individual convicted under this section of an offense for which a mandatory minimum term of imprisonment is applicable shall not be eligible for parole under section 4202 of title 18[2] until the individual has served the mandatory term of imprisonment as enhanced by this section.

**(f) Distribution of controlled substance to pregnant individual**

Except as authorized by this subchapter, it shall be unlawful for any person to knowingly or intentionally provide or distribute any controlled substance to a pregnant individual in violation of any provision of this subchapter. Any person who violates this subsection shall be subject to the provisions of subsections (b), (c), and (e) of this section.

(Pub. L. 91–513, title II, § 420, formerly § 405B, as added Pub. L. 99–570, title I, § 1102, Oct. 27, 1986, 100 Stat. 3207–10; amended Pub. L. 100–690, title VI, §§ 6452(b)(1), 6459, 6470(d), Nov. 18, 1988, 102 Stat. 4371, 4373, 4378; renumbered § 420 and amended Pub. L. 101–647, title X, §§ 1002(c), 1003(c), title XXXV, § 3599L, Nov. 29, 1990, 104 Stat. 4827, 4829, 4932.)

REFERENCES IN TEXT

Section 4202 of title 18, referred to in subsec. (e), which, as originally enacted in Title 18, Crimes and Criminal Procedure, related to eligibility of prisoners for parole, was repealed and a new section 4202 enacted as part of the repeal and enactment of a new chapter 311 (§ 4201 et seq.) of Title 18, by Pub. L. 94–233, § 2, Mar. 15, 1976, 90 Stat. 219. For provisions relating to the eligibility of prisoners for parole, see section 4205 of Title 18. Pub. L. 98–473, title II, §§ 218(a)(5), 235(a)(1), (b)(1), Oct. 12, 1984, 98 Stat. 2027, 2031, 2032, as amended, provided that, effective on the first day of the first calendar month beginning 36 months after Oct. 12, 1984 (Nov. 1, 1987), chapter 311 of Title 18 is repealed, subject to remaining effective for five years after Nov. 1, 1987, in certain circumstances. See Effective Date note set out under section 3551 of Title 18.

CODIFICATION

Section was classified to section 845b of this title prior to renumbering by Pub. L. 101–647.

AMENDMENTS

1990—Subsec. (b). Pub. L. 101–647, § 1003(c)(1), which directed the substitution of ''is subject to twice the maximum punishment otherwise authorized'' for ''is punishable by a term of imprisonment up to twice that authorized, or up to twice the fine authorized, or both,'' was executed by making the substitution for ''is punishable by a term of imprisonment up to twice that otherwise authorized, or up to twice the fine otherwise authorized, or both,'' to reflect the probable intent of Congress.

Subsec. (c). Pub. L. 101–647, § 3599L, substituted ''has become final'' for ''have become final''.

Pub. L. 101–647, § 1003(c)(2), which directed the substitution of ''is subject to three times the maximum punishment otherwise authorized'' for ''is punishable by a term of imprisonment up to three times that authorized, or up to three times the fine authorized, or both,'' was executed by making the substitution for ''is punishable by a term of imprisonment up to three times that otherwise authorized, or up to three times the fine otherwise authorized, or both,'' to reflect the probable intent of Congress.

1988—Subsec. (a)(3). Pub. L. 100–690, § 6459, added par. (3).

Subsec. (c). Pub. L. 100–690, § 6452(b)(1), struck out ''or convictions'' after ''a prior conviction'' and inserted at end ''Penalties for third and subsequent convictions shall be governed by section 841(b)(1)(A) of this title.''

Subsec. (e). Pub. L. 100–690, § 6470(d), struck out ''required by section 841(b) of this title'' after ''mandatory term of imprisonment''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 841 of this title; title 18 section 3592.

## § 862. Denial of Federal benefits to drug traffickers and possessors

**(a) Drug traffickers**

(1) Any individual who is convicted of any Federal or State offense consisting of the distribution of controlled substances shall—

(A) at the discretion of the court, upon the first conviction for such an offense be ineligible for any or all Federal benefits for up to 5 years after such conviction;

(B) at the discretion of the court, upon a second conviction for such an offense be ineligible for any or all Federal benefits for up to 10 years after such conviction; and

(C) upon a third or subsequent conviction for such an offense be permanently ineligible for all Federal benefits.

(2) The benefits which are denied under this subsection shall not include benefits relating to long-term drug treatment programs for addiction for any person who, if there is a reasonable body of evidence to substantiate such declara-

[1] So in original. Probably should be followed by a dash.

[2] See References in Text note below.

tion, declares himself to be an addict and submits himself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary of Health and Human Services.

**(b) Drug possessors**

(1) Any individual who is convicted of any Federal or State offense involving the possession of a controlled substance (as such term is defined for purposes of this subchapter) shall—

(A) upon the first conviction for such an offense and at the discretion of the court—

(i) be ineligible for any or all Federal benefits for up to one year;

(ii) be required to successfully complete an approved drug treatment program which includes periodic testing to insure that the individual remains drug free;

(iii) be required to perform appropriate community service; or

(iv) any combination of clause (i), (ii), or (iii); and

(B) upon a second or subsequent conviction for such an offense be ineligible for all Federal benefits for up to 5 years after such conviction as determined by the court. The court shall continue to have the discretion in subparagraph (A) above. In imposing penalties and conditions under subparagraph (A), the court may require that the completion of the conditions imposed by clause (ii) or (iii) be a requirement for the reinstatement of benefits under clause (i).

(2) The penalties and conditions which may be imposed under this subsection shall be waived in the case of a person who, if there is a reasonable body of evidence to substantiate such declaration, declares himself to be an addict and submits himself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary of Health and Human Services.

**(c) Suspension of period of ineligibility**

The period of ineligibility referred to in subsections (a) and (b) of this section shall be suspended if the individual—

(A) completes a supervised drug rehabilitation program after becoming ineligible under this section;

(B) has otherwise been rehabilitated; or

(C) has made a good faith effort to gain admission to a supervised drug rehabilitation program, but is unable to do so because of inaccessibility or unavailability of such a program, or the inability of the individual to pay for such a program.

**(d) Definitions**

As used in this section—

(1) the term ''Federal benefit''—

(A) means the issuance of any grant, contract, loan, professional license, or commercial license provided by an agency of the United States or by appropriated funds of the United States; and

(B) does not include any retirement, welfare, Social Security, health, disability, veterans benefit, public housing, or other similar benefit, or any other benefit for which payments or services are required for eligibility; and

(2) the term ''veterans benefit'' means all benefits provided to veterans, their families, or survivors by virtue of the service of a veteran in the Armed Forces of the United States.

**(e) Inapplicability of this section to Government witnesses**

The penalties provided by this section shall not apply to any individual who cooperates or testifies with the Government in the prosecution of a Federal or State offense or who is in a Government witness protection program.

**(f) Indian provision**

Nothing in this section shall be construed to affect the obligation of the United States to any Indian or Indian tribe arising out of any treaty, statute, Executive order, or the trust responsibility of the United States owing to such Indian or Indian tribe. Nothing in this subsection shall exempt any individual Indian from the sanctions provided for in this section, provided that no individual Indian shall be denied any benefit under Federal Indian programs comparable to those described in subsection (d)(1)(B) or (d)(2) of this section.

**(g) Presidential report**

(1) On or before May 1, 1989, the President shall transmit to the Congress a report—

(A) delineating the role of State courts in implementing this section;

(B) describing the manner in which Federal agencies will implement and enforce the requirements of this section;

(C) detailing the means by which Federal and State agencies, courts, and law enforcement agencies will exchange and share the data and information necessary to implement and enforce the withholding of Federal benefits; and

(D) recommending any modifications to improve the administration of this section or otherwise achieve the goal of discouraging the trafficking and possession of controlled substances.

(2) No later than September 1, 1989, the Congress shall consider the report of the President and enact such changes as it deems appropriate to further the goals of this section.

**(h) Effective date**

The denial of Federal benefits set forth in this section shall take effect for convictions occurring after September 1, 1989.

(Pub. L. 91–513, title II, § 421, formerly Pub. L. 100–690, title V, § 5301, Nov. 18, 1988, 102 Stat. 4310; renumbered § 421 of Pub. L. 91–513 and amended Pub. L. 101–647, title X, § 1002(d), Nov. 29, 1990, 104 Stat. 4827.)

CODIFICATION

Section was classified to section 853a of this title prior to renumbering by Pub. L. 101–647.

AMENDMENTS

1990—Pub. L. 101–647, § 1002(d)(1), renumbered section 853a of this title as this section.

Subsec. (a)(1). Pub. L. 101–647, § 1002(d)(2), struck out ''(as such terms are defined for purposes of the Con-

trolled Substances Act)'' after ''controlled substances'' in introductory provisions.

## § 863. Drug paraphernalia

### (a) In general

It is unlawful for any person—

(1) to sell or offer for sale drug paraphernalia;

(2) to use the mails or any other facility of interstate commerce to transport drug paraphernalia; or

(3) to import or export drug paraphernalia.

### (b) Penalties

Anyone convicted of an offense under subsection (a) of this section shall be imprisoned for not more than three years and fined under title 18.

### (c) Seizure and forfeiture

Any drug paraphernalia involved in any violation of subsection (a) of this section shall be subject to seizure and forfeiture upon the conviction of a person for such violation. Any such paraphernalia shall be delivered to the Administrator of General Services, General Services Administration, who may order such paraphernalia destroyed or may authorize its use for law enforcement or educational purposes by Federal, State, or local authorities.

### (d) "Drug paraphernalia" defined

The term ''drug paraphernalia'' means any equipment, product, or material of any kind which is primarily intended or designed for use in manufacturing, compounding, converting, concealing, producing, processing, preparing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance, possession of which is unlawful under this subchapter. It includes items primarily intended or designed for use in ingesting, inhaling, or otherwise introducing marijuana,[1] cocaine, hashish, hashish oil, PCP, or amphetamines into the human body, such as—

(1) metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;

(2) water pipes;

(3) carburetion tubes and devices;

(4) smoking and carburetion masks;

(5) roach clips: meaning objects used to hold burning material, such as a marihuana cigarette, that has become too small or too short to be held in the hand;

(6) miniature spoons with level capacities of one-tenth cubic centimeter or less;

(7) chamber pipes;

(8) carburetor pipes;

(9) electric pipes;

(10) air-driven pipes;

(11) chillums;

(12) bongs;

(13) ice pipes or chillers;

(14) wired cigarette papers; or

(15) cocaine freebase kits.

### (e) Matters considered in determination of what constitutes drug paraphernalia

In determining whether an item constitutes drug paraphernalia, in addition to all other logically relevant factors, the following may be considered:

(1) instructions, oral or written, provided with the item concerning its use;

(2) descriptive materials accompanying the item which explain or depict its use;

(3) national and local advertising concerning its use;

(4) the manner in which the item is displayed for sale;

(5) whether the owner, or anyone in control of the item, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;

(6) direct or circumstantial evidence of the ratio of sales of the item(s) to the total sales of the business enterprise;

(7) the existence and scope of legitimate uses of the item in the community; and

(8) expert testimony concerning its use.

### (f) Exemptions

This section shall not apply to—

(1) any person authorized by local, State, or Federal law to manufacture, possess, or distribute such items; or

(2) any item that, in the normal lawful course of business, is imported, exported, transported, or sold through the mail or by any other means, and traditionally intended for use with tobacco products, including any pipe, paper, or accessory.

(Pub. L. 91–513, title II, § 422(a), as added Pub. L. 101–647, title XXIV, § 2401(a), Nov. 29, 1990, 104 Stat. 4858; Pub. L. 91–513, title II, § 422(b)–(f), formerly Pub. L. 99–570, title I, § 1822(b)–(f), Oct. 27, 1986, 100 Stat. 3207–51, amended Pub. L. 100–690, title VI, § 6485, Nov. 18, 1988, 102 Stat. 4384; renumbered § 422(b)–(f) of Pub. L. 91–513; amended Pub. L. 101–647, title XXIV, § 2401(b), (c), Nov. 29, 1990, 104 Stat. 4859.)

CODIFICATION

Pub. L. 101–647, § 2401(b), transferred section 1822(b) to (f) of Pub. L. 99–570, which was classified to section 857 of this title, to subsecs. (b) to (f) of this section.

AMENDMENTS

1990—Subsec. (b). Pub. L. 101–647, § 2401(c)(1), substituted ''fined under title 18'' for ''fined not more than $100,000''.

Pub. L. 101–647, § 2401(b), redesignated subsec. (b) of section 857 of this title as subsec. (b) of this section.

Subsecs. (c) to (e). Pub. L. 101–647, § 2401(b), redesignated subsecs. (c) to (e) of section 857 of this title as subsecs. (c) to (e) of this section.

Subsec. (f). Pub. L. 101–647, § 2401(c)(2), made technical amendment to reference to ''This section'' to correct reference to corresponding provision of original act.

Pub. L. 101–647, § 2401(b), redesignated subsec. (f) of section 857 of this title as subsec. (f) of this section.

1988—Subsec. (d) [formerly § 857(d)]. Pub. L. 100–690, § 6485(1), substituted '', possession of which is unlawful under the Controlled Substances Act'' for ''in violation of the Controlled Substances Act''. See 1990 Amendment note above.

Subsec. (f)(2) [formerly § 857(f)(2)]. Pub. L. 100–690, § 6485(2), substituted ''traditionally'' for ''primarily'' before ''intended for use with''. See 1990 Amendment note above.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 881 of this title; title 18 section 1956.

[1] So in original. Probably should be ''marihuana,''.

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

PART REFERRED TO IN OTHER SECTIONS

This part is referred to in section 965 of this title.

### § 871. Attorney General

**(a) Delegation of functions**

The Attorney General may delegate any of his functions under this subchapter to any officer or employee of the Department of Justice.

**(b) Rules and regulations**

The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.

**(c) Acceptance of devices, bequests, gifts, and donations**

The Attorney General may accept in the name of the Department of Justice any form of device, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

(Pub. L. 91–513, title II, § 501, Oct. 27, 1970, 84 Stat. 1270.)

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (a) and (b), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

### § 872. Education and research programs of Attorney General

**(a) Authorization**

The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this subchapter. Such programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, and Federal personnel;

(2) studies or special projects designed to compare the deterrent effects of various enforcement strategies on drug use and abuse;

(3) studies or special projects designed to assess and detect accurately the presence in the human body of drugs or other substances which are or may be subject to control under this subchapter, including the development of rapid field identification methods which would enable agents to detect microquantities of such drugs or other substances;

(4) studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country;

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; and

(6) studies or special projects to develop information necessary to carry out his functions under section 811 of this title.

**(b) Contracts**

The Attorney General may enter into contracts for such educational and research activities without performance bonds and without regard to section 5 of title 41.

**(c) Identification of research populations; authorization to withhold**

The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which such authorization was obtained.

**(d) Affect of treaties and other international agreements on confidentiality**

Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit, modify, or prevent the protection of the confidentiality of patient records or of the names and other identifying characteristics of research subjects as provided by any Federal, State, or local law or regulation.

**(e) Use of controlled substances in research**

The Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General.

**(f) Program to curtail diversion of precursor and essential chemicals**

The Attorney General shall maintain an active program, both domestic and international, to curtail the diversion of precursor chemicals and essential chemicals used in the illicit manufacture of controlled substances.

(Pub. L. 91–513, title II, § 502, Oct. 27, 1970, 84 Stat. 1271; Pub. L. 95–633, title I, § 108(a), Nov. 10, 1978, 92 Stat. 3773; Pub. L. 100–690, title VI, § 6060, Nov. 18, 1988, 102 Stat. 4320.)

AMENDMENTS

1988—Subsec. (f). Pub. L. 100–690 added subsec. (f).

1978—Subsecs. (d), (e). Pub. L. 95–633 added subsec. (d) and redesignated former subsec. (d) as (e).

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112

of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

## § 873. Cooperative arrangements

### (a) Cooperation of Attorney General with local, State, and Federal agencies

The Attorney General shall cooperate with local, State, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is authorized to—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the several States;

(3) conduct training programs on controlled substance law enforcement for local, State, and Federal personnel;

(4) maintain in the Department of Justice a unit which will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, which may be received from Federal, State, and local agencies, and make such information available for Federal, State, and local law enforcement purposes;

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted;

(6) assist State and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by—

(A) making periodic assessments of the capabilities of State and local governments to adequately control the diversion of controlled substances;

(B) providing advice and counsel to State and local governments on the methods by which such governments may strengthen their controls against diversion; and

(C) establishing cooperative investigative efforts to control diversion; and

(7) notwithstanding any other provision of law, enter into contractual agreements with State and local law enforcement agencies to provide for cooperative enforcement and regulatory activities under this chapter.[1]

### (b) Requests by Attorney General for assistance from Federal agencies or instrumentalities

When requested by the Attorney General, it shall be the duty of any agency or instrumentality of the Federal Government to furnish assistance, including technical advice, to him for carrying out his functions under this subchapter; except that no such agency or instrumentality shall be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

[1] See References in Text note below.

### (c) Descriptive and analytic reports by Attorney General to State agencies of distribution patterns of schedule II substances having highest rates of abuse

The Attorney General shall annually (1) select the controlled substances (or controlled substances) contained in schedule II which, in the Attorney General's discretion, is determined to have the highest rate of abuse, and (2) prepare and make available to regulatory, licensing, and law enforcement agencies of States descriptive and analytic reports on the actual distribution patterns in such States of each such controlled substance.

### (d) Grants by Attorney General

(1) The Attorney General may make grants, in accordance with paragraph (2), to State and local governments to assist in meeting the costs of—

(A) collecting and analyzing data on the diversion of controlled substances,

(B) conducting investigations and prosecutions of such diversions,

(C) improving regulatory controls and other authorities to control such diversions,

(D) programs to prevent such diversions,

(E) preventing and detecting forged prescriptions, and

(F) training law enforcement and regulatory personnel to improve the control of such diversions.

(2) No grant may be made under paragraph (1) unless an application therefor is submitted to the Attorney General in such form and manner as the Attorney General may prescribe. No grant may exceed 80 per centum of the costs for which the grant is made, and no grant may be made unless the recipient of the grant provides assurances satisfactory to the Attorney General that it will obligate funds to meet the remaining 20 per centum of such costs. The Attorney General shall review the activities carried out with grants under paragraph (1) and shall report annually to Congress on such activities.

(3) To carry out this subsection there is authorized to be appropriated $6,000,000 for fiscal year 1985 and $6,000,000 for fiscal year 1986.

(Pub. L. 91–513, title II, § 503, Oct. 27, 1970, 84 Stat. 1271; Pub. L. 96–359, § 8(a) Sept. 26, 1980, 94 Stat. 1194; Pub. L. 98–473, title II, § 517, Oct. 12, 1984, 98 Stat. 2074; Pub. L. 99–570, title I, § 1868, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, § 85, Nov. 10, 1986, 100 Stat. 3620.)

REFERENCES IN TEXT

This chapter, referred to in subsec. (a)(7), was in the original as added by Pub. L. 99–646 "this Act", meaning Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236, as amended. In the subsec. (a)(7) added by Pub. L. 99–570, the reference was "this title", meaning title II of Pub. L. 91–513 which is popularly known as the "Controlled Substances Act" and is classified principally to this subchapter. For complete classification of this Act and title II to the Code, see Short Title note set out under section 801 of this title and Tables.

Schedule II, referred to in subsec. (c), is set out in section 812(c) of this title.

AMENDMENTS

1986—Subsec. (a)(7). Pub. L. 99–570 and Pub. L. 99–646 made substantially identical amendment, adding par. (7).

1984—Subsec. (a)(6). Pub. L. 98–473, § 517(a), added par. (6).

Subsec. (d). Pub. L. 98–473, § 517(b), added subsec. (d).

1980—Subsec. (c). Pub. L. 96–359 added subsec. (c).

NATIONAL DRUG INTELLIGENCE CENTER

Pub. L. 103–139, title VIII, § 8056, Nov. 11, 1993, 107 Stat. 1452, provided that: ''During the current fiscal year and thereafter, there is established, under the direction and control of the Attorney General, the National Drug Intelligence Center, whose mission it shall be to coordinate and consolidate drug intelligence from all national security and law enforcement agencies, and produce information regarding the structure, membership, finances, communications, and activities of drug trafficking organizations: *Provided*, That funding for the operation of the National Drug Intelligence Center, including personnel costs associated therewith, shall be provided from the funds appropriated to the Department of Defense.''

Similar provisions were contained in the following prior appropriation act:

Pub. L. 102–396, title IX, § 9078, Oct. 6, 1992, 106 Stat. 1919.

### § 874. Advisory committees

The Attorney General may from time to time appoint committees to advise him with respect to preventing and controlling the abuse of controlled substances. Members of the committees may be entitled to receive compensation at the rate of $100 for each day (including traveltime) during which they are engaged in the actual performance of duties. While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5.

(Pub. L. 91–513, title II, § 504, Oct. 27, 1970, 84 Stat. 1272.)

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

### § 875. Administrative hearings

#### (a) Power of Attorney General

In carrying out his functions under this subchapter, the Attorney General may hold hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

#### (b) Procedures applicable

Except as otherwise provided in this subchapter, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5 of title 5.

(Pub. L. 91–513, title II, § 505, Oct. 27, 1970, 84 Stat. 1272.)

### § 876. Subpenas

#### (a) Authorization of use by Attorney General

In any investigation relating to his functions under this subchapter with respect to controlled substances, listed chemicals, tableting machines, or encapsulating machines, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

#### (b) Service

A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered a true copy thereof by the person serving it shall be proof of service.

#### (c) Enforcement

In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

(Pub. L. 91–513, title II, § 506, Oct. 27, 1970, 84 Stat. 1272; Pub. L. 100–690, title VI, § 6058, Nov. 18, 1988, 102 Stat. 4319.)

AMENDMENTS

1988—Subsec. (a). Pub. L. 100–690 inserted ''listed chemicals, tableting machines, or encapsulating machines,'' after ''with respect to controlled substances,''.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 880 of this title.

### § 877. Judicial review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

(Pub. L. 91–513, title II, § 507, Oct. 27, 1970, 84 Stat. 1273.)

### § 878. Powers of enforcement personnel

(a) Any officer or employee of the Drug Enforcement Administration or any State or local law enforcement officer designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this subchapter; and

(5) perform such other law enforcement duties as the Attorney General may designate.

(b) State and local law enforcement officers performing functions under this section shall not be deemed Federal employees and shall not be subject to provisions of law relating to Federal employees, except that such officers shall be subject to section 3374(c) of title 5.

(Pub. L. 91–513, title II, § 508, Oct. 27, 1970, 84 Stat. 1273; Pub. L. 96–132, § 16(b), Nov. 30, 1979, 93 Stat. 1049; Pub. L. 99–570, title I, § 1869, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, § 86, Nov. 10, 1986, 100 Stat. 3620.)

AMENDMENTS

1986—Pub. L. 99–570 and Pub. L. 99–646 amended section substantially identically designating existing provisions as subsec. (a) and adding subsec. (b), with the exception of the amendment of subsec. (a) for which Pub. L. 99–570 directed the insertion of ''or (with respect to offenses under this subchapter or subchapter II of this chapter) any State or local law enforcement officer'' and Pub. L. 99–646 directed the insertion of ''or any State or local law enforcement officer'', the latter of which was executed to reflect the probable intent of Congress.

1979—Pub. L. 96–132 substituted ''Drug Enforcement Administration'' for ''Bureau of Narcotics and Dangerous Drugs''.

### § 879. Search warrants

A search warrant relating to offenses involving controlled substances may be served at any time of the day or night if the judge or United States magistrate judge issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service at such time.

(Pub. L. 91–513, title II, § 509, Oct. 27, 1970, 84 Stat. 1274; Pub. L. 93–481, § 3, Oct. 26, 1974, 88 Stat. 1455; Pub. L. 101–650, title III, § 321, Dec. 1, 1990, 104 Stat. 5117.)

AMENDMENTS

1974—Pub. L. 93–481 struck out designation ''(a)'' before ''A search warrant'', and struck out subsec. (b) which permitted officers authorized to execute search warrants to break open and enter premises under certain circumstances and which required that such officers identify themselves and give reasons and authority for their entry after such entry.

CHANGE OF NAME

''United States magistrate judge'' substituted in text for ''United States magistrate'' pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure.

### § 880. Administrative inspections and warrants

#### (a) "Controlled premises" defined

As used in this section, the term ''controlled premises'' means—

(1) places where original or other records or documents required under this subchapter are kept or required to be kept, and

(2) places, including factories, warehouses, and other establishments, and conveyances, where persons registered under section 823 of this title (or exempt from registration under section 822(d) of this title or by regulation of the Attorney General) or regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.

#### (b) Grant of authority; scope of inspections

(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this subchapter and otherwise facilitating the carrying out of his functions under this subchapter, the Attorney General is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as ''inspectors'') designated by the Attorney General. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this subchapter;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs, listed chemicals, and other substances or materials, containers, and labeling found therein, and, except as provided in paragraph (4) of this subsection, all other things therein (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in clause (A) or otherwise bearing on the provisions of this subchapter; and

(C) to inventory any stock of any controlled substance or listed chemical therein and obtain samples of any such substance or chemical.

(4) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

**(c) Situations not requiring warrants**

A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpena issued in accordance with section 876 of this title, nor for entries and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(5) in any other situations where a warrant is not constitutionally required.

**(d) Administrative inspection warrants; issuance; execution; probable cause**

Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of the United States or of a State court of record, or any United States magistrate judge, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this subchapter or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term ''probable cause'' means a valid public interest in the effective enforcement of this subchapter or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate judge and establishing the grounds for issuing the warrant. If the judge or magistrate judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b)(2) of this section to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate judge to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate judge allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate judge, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and the applicant for the warrant.

(4) The judge or magistrate judge who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

(Pub. L. 91–513, title II, § 510, Oct. 27, 1970, 84 Stat. 1274; Pub. L. 101–647, title XXXV, § 3599M, Nov. 29, 1990, 104 Stat. 4932; Pub. L. 101–650, title III, § 321, Dec. 1, 1990, 104 Stat. 5117; Pub. L. 103–200, § 6, Dec. 17, 1993, 107 Stat. 2339.)

AMENDMENTS

1993—Subsec. (a)(2). Pub. L. 103–200, § 6(1), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''places, including factories, warehouses, or other establishments, and conveyances, where persons registered under section 823 of this title (or exempted from registration under section 822(d) of this title) may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances.''

Subsec. (b)(3)(B). Pub. L. 103–200, § 6(2)(A), inserted '', listed chemicals,'' after ''unfinished drugs''.

Subsec. (b)(3)(C). Pub. L. 103–200, § 6(2)(B), inserted ''or listed chemical'' after ''controlled substance'' and ''or chemical'' after ''such substance''.

1990—Subsec. (b)(3)(B). Pub. L. 101–647 substituted ''paragraph (4)'' for ''paragraph (5)''.

CHANGE OF NAME

''United States magistrate judge'' and ''magistrate judge'' substituted for ''United States magistrate'' and ''magistrate'', respectively, wherever appearing in subsec. (d) pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 965 of this title.

## § 881. Forfeitures

### (a) Subject property

The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this subchapter.

(2) All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this subchapter.

(3) All property which is used, or intended for use, as a container for property described in paragraph (1), (2), or (9).

(4) All conveyances, including aircraft, vehicles, or vessels, which are used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1), (2), or (9), except that—

(A) no conveyance used by any person as a common carrier in the transaction of business as a common carrier shall be forfeited under the provisions of this section unless it shall appear that the owner or other person in charge of such conveyance was a consenting party or privy to a violation of this subchapter or subchapter II of this chapter;

(B) no conveyance shall be forfeited under the provisions of this section by reason of any act or omission established by the owner thereof to have been committed or omitted by any person other than such owner while such conveyance was unlawfully in the possession of a person other than the owner in violation of the criminal laws of the United States, or of any State; and

(C) no conveyance shall be forfeited under this paragraph to the extent of an interest of an owner, by reason of any act or omission established by that owner to have been committed or omitted without the knowledge, consent, or willful blindness of the owner.

(5) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this subchapter.

(6) All moneys, negotiable instruments, securities, or other things of value furnished or intended to be furnished by any person in exchange for a controlled substance in violation of this subchapter, all proceeds traceable to such an exchange, and all moneys, negotiable instruments, and securities used or intended to be used to facilitate any violation of this subchapter, except that no property shall be forfeited under this paragraph, to the extent of the interest of an owner, by reason of any act or omission established by that owner to have been committed or omitted without the knowledge or consent of that owner.

(7) All real property, including any right, title, and interest (including any leasehold interest) in the whole of any lot or tract of land and any appurtenances or improvements, which is used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, a violation of this subchapter punishable by more than one year's imprisonment, except that no property shall be forfeited under this paragraph, to the extent of an interest of an owner, by reason of any act or omission established by that owner to have been committed or omitted without the knowledge or consent of that owner.

(8) All controlled substances which have been possessed in violation of this subchapter.

(9) All listed chemicals, all drug manufacturing equipment, all tableting machines, all encapsulating machines, and all gelatin capsules, which have been imported, exported, manufactured, possessed, distributed, or intended to be distributed, imported, or exported, in violation of a felony provision of this subchapter or subchapter II of this chapter.

(10) Any drug paraphernalia (as defined in section 1822 of the Mail Order Drug Paraphernalia Control Act).[1]

(11) Any firearm (as defined in section 921 of title 18) used or intended to be used to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1) or (2) and any proceeds traceable to such property.

### (b) Seizure pursuant to Supplemental Rules for Certain Admiralty and Maritime Claims; issuance of warrant authorizing seizure

Any property subject to civil forfeiture to the United States under this subchapter may be seized by the Attorney General upon process issued pursuant to the Supplemental Rules for Certain Admiralty and Maritime Claims by any

[1] See References in Text note below.

district court of the United States having jurisdiction over the property, except that seizure without such process may be made when—

(1) the seizure is incident to an arrest or a search under a search warrant or an inspection under an administrative inspection warrant;

(2) the property subject to seizure has been the subject of a prior judgment in favor of the United States in a criminal injunction or forfeiture proceeding under this subchapter;

(3) the Attorney General has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or

(4) the Attorney General has probable cause to believe that the property is subject to civil forfeiture under this subchapter.

In the event of seizure pursuant to paragraph (3) or (4) of this subsection, proceedings under subsection (d) of this section shall be instituted promptly.

The Government may request the issuance of a warrant authorizing the seizure of property subject to forfeiture under this section in the same manner as provided for a search warrant under the Federal Rules of Criminal Procedure.

**(c) Custody of Attorney General**

Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, subject only to the orders and decrees of the court or the official having jurisdiction thereof. Whenever property is seized under any of the provisions of this subchapter, the Attorney General may—

(1) place the property under seal;

(2) remove the property to a place designated by him; or

(3) require that the General Services Administration take custody of the property and remove it, if practicable, to an appropriate location for disposition in accordance with law.

**(d) Other laws and proceedings applicable**

The provisions of law relating to the seizure, summary and judicial forfeiture, and condemnation of property for violation of the customs laws; the disposition of such property or the proceeds from the sale thereof; the remission or mitigation of such forfeitures; and the compromise of claims shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under any of the provisions of this subchapter, insofar as applicable and not inconsistent with the provisions hereof; except that such duties as are imposed upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this subchapter by such officers, agents, or other persons as may be authorized or designated for that purpose by the Attorney General, except to the extent that such duties arise from seizures and forfeitures effected by any customs officer.

**(e) Disposition of forfeited property**

(1) Whenever property is civilly or criminally forfeited under this subchapter the Attorney General may—

(A) retain the property for official use or, in the manner provided with respect to transfers under section 1616a of title 19, transfer the property to any Federal agency or to any State or local law enforcement agency which participated directly in the seizure or forfeiture of the property;

(B) except as provided in paragraph (4), sell, by public sale or any other commercially feasible means, any forfeited property which is not required to be destroyed by law and which is not harmful to the public;

(C) require that the General Services Administration take custody of the property and dispose of it in accordance with law;

(D) forward it to the Bureau of Narcotics and Dangerous Drugs for disposition (including delivery for medical or scientific use to any Federal or State agency under regulations of the Attorney General); or

(E) transfer the forfeited personal property or the proceeds of the sale of any forfeited personal or real property to any foreign country which participated directly or indirectly in the seizure or forfeiture of the property, if such a transfer—

(i) has been agreed to by the Secretary of State;

(ii) is authorized in an international agreement between the United States and the foreign country; and

(iii) is made to a country which, if applicable, has been certified under section 2291j(b) of title 22.

(2)(A) The proceeds from any sale under subparagraph (B) of paragraph (1) and any moneys forfeited under this subchapter shall be used to pay—

(i) all property expenses of the proceedings for forfeiture and sale including expenses of seizure, maintenance of custody, advertising, and court costs; and

(ii) awards of up to $100,000 to any individual who provides original information which leads to the arrest and conviction of a person who kills or kidnaps a Federal drug law enforcement agent.

Any award paid for information concerning the killing or kidnapping of a Federal drug law enforcement agent, as provided in clause (ii), shall be paid at the discretion of the Attorney General.

(B) The Attorney General shall forward to the Treasurer of the United States for deposit in accordance with section 524(c) of title 28, any amounts of such moneys and proceeds remaining after payment of the expenses provided in subparagraph (A), except that, with respect to forfeitures conducted by the Postal Service, the Postal Service shall deposit in the Postal Service Fund, under section 2003(b)(7) of title 39, such moneys and proceeds.

(3) The Attorney General shall assure that any property transferred to a State or local law enforcement agency under paragraph (1)(A)—

(A) has a value that bears a reasonable relationship to the degree of direct participation of the State or local agency in the law enforcement effort resulting in the forfeiture, taking into account the total value of all property forfeited and the total law enforcement effort with respect to the violation of law on which the forfeiture is based; and

(B) will serve to encourage further cooperation between the recipient State or local agency and Federal law enforcement agencies.

(4)(A) With respect to real property described in subparagraph (B), if the chief executive officer of the State involved submits to the Attorney General a request for purposes of such subparagraph, the authority established in such subparagraph is in lieu of the authority established in paragraph (1)(B).

(B) In the case of property described in paragraph (1)(B) that is civilly or criminally forfeited under this subchapter, if the property is real property that is appropriate for use as a public area reserved for recreational or historic purposes or for the preservation of natural conditions, the Attorney General, upon the request of the chief executive officer of the State in which the property is located, may transfer title to the property to the State, either without charge or for a nominal charge, through a legal instrument providing that—

(i) such use will be the principal use of the property; and

(ii) title to the property reverts to the United States in the event that the property is used otherwise.

**(f) Forfeiture and destruction of schedule I and II substances**

(1) All controlled substances in schedule I or II that are possessed, transferred, sold, or offered for sale in violation of the provisions of this subchapter; all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2) of this section; and any equipment or container subject to forfeiture under subsection (a)(2) or (3) of this section which cannot be separated safely from such raw materials or products shall be deemed contraband and seized and summarily forfeited to the United States. Similarly, all substances in schedule I or II, which are seized or come into the possession of the United States, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the United States.

(2) The Attorney General may direct the destruction of all controlled substances in schedule I or II seized for violation of this subchapter; all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2) of this section; and any equipment or container subject to forfeiture under subsection (a)(2) or (3) of this section which cannot be separated safely from such raw materials or products under such circumstances as the Attorney General may deem necessary.

**(g) Plants**

(1) All species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this subchapter, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the United States.

(2) The failure, upon demand by the Attorney General or his duly authorized agent, of the person in occupancy or in control of land or premises upon which such species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, shall constitute authority for the seizure and forfeiture.

(3) The Attorney General, or his duly authorized agent, shall have authority to enter upon any lands, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy such plants.

**(h) Vesting of title in United States**

All right, title, and interest in property described in subsection (a) of this section shall vest in the United States upon commission of the act giving rise to forfeiture under this section.

**(i) Stay of civil forfeiture proceedings**

The filing of an indictment or information alleging a violation of this subchapter or subchapter II of this chapter, or a violation of State or local law that could have been charged under this subchapter or subchapter II of this chapter, which is also related to a civil forfeiture proceeding under this section shall, upon motion of the United States and for good cause shown, stay the civil forfeiture proceeding.

**(j) Venue**

In addition to the venue provided for in section 1395 of title 28 or any other provision of law, in the case of property of a defendant charged with a violation that is the basis for forfeiture of the property under this section, a proceeding for forfeiture under this section may be brought in the judicial district in which the defendant owning such property is found or in the judicial district in which the criminal prosecution is brought.

**(*l*)[2] Agreement between Attorney General and Postal Service for performance of functions**

The functions of the Attorney General under this section shall be carried out by the Postal Service pursuant to such agreement as may be entered into between the Attorney General and the Postal Service.

(Pub. L. 91–513, title II, § 511, Oct. 27, 1970, 84 Stat. 1276; Pub. L. 95–633, title III, § 301(a), Nov. 10, 1978, 92 Stat. 3777; Pub. L. 96–132, § 14, Nov. 30, 1979, 93 Stat. 1048; Pub. L. 98–473, title II, §§ 306, 309, 518, Oct. 12, 1984, 98 Stat. 2050, 2051, 2075; Pub. L. 99–570, title I, §§ 1006(c), 1865, 1992, Oct. 27, 1986, 100 Stat. 3207–7, 3207–54, 3207–59; Pub. L. 99–646, § 74, Nov. 10, 1986, 100 Stat. 3618; Pub. L. 100–690, title V, § 5105, title VI, §§ 6059, 6074, 6075, 6077(a), (b), 6253, Nov. 18, 1988, 102 Stat. 4301, 4319, 4323–4325, 4363; Pub. L. 101–189, div. A, title XII, § 1215(a), Nov. 29, 1989, 103 Stat. 1569; Pub. L. 101–647, title XX, §§ 2003, 2004, 2007, 2008, Nov. 29, 1990, 104 Stat. 4855, 4856; Pub. L. 102–239, § 2, Dec. 17, 1991, 105 Stat. 1912; Pub. L. 103–447, title I, § 102(d), Nov. 2, 1994, 108 Stat. 4693.)

REFERENCES IN TEXT

Subchapter II of this chapter, referred to in subsecs. (a)(4)(A), (9), and (i), was in the original "title III", meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

[2] So in original. No subsec. (k) has been enacted.

Section 1822 of the Mail Order Drug Paraphernalia Control Act, referred to in subsec. (a)(10), is section 1822 of Pub. L. 99–570, title I, Oct. 27, 1986, 100 Stat. 3207–51, which was repealed by Pub. L. 101–647, title XXIV, §2401(d), Nov. 29, 1990, 104 Stat. 4859. Prior to repeal, subsec. (d) of section 1822 of Pub. L. 99–570, which defined ''drug paraphernalia'', was transferred to subsec. (d) of section 422 of title II of Pub. L. 91–513, the Controlled Substances Act. Section 422 of Pub. L. 91–513 is classified to section 863 of this title.

The Federal Rules of Criminal Procedure, referred to in subsec. (b), are set out in the Appendix to Title 18, Crimes and Criminal Procedure.

The customs laws, referred to in subsec. (d), are classified generally to Title 19, Customs Duties.

Schedules I and II, referred to in subsecs. (f) and (g), are set out in section 812(c) of this title.

AMENDMENTS

1994—Subsec. (e)(1)(E)(iii). Pub. L. 103–447 substituted ''section 2291j(b) of title 22'' for ''section 2291(h) of title 22''.

1991—Subsec. (e)(1)(B). Pub. L. 102–239, §2(1), substituted ''except as provided in paragraph (4), sell'' for ''sell''.

Subsec. (e)(4). Pub. L. 102–239, §2(2), added par. (4).

1990—Subsec. (a)(10). Pub. L. 101–647, §2007, added par. (10).

Subsec. (a)(11). Pub. L. 101–647, §2008, added par. (11).

Subsec. (e)(1)(B). Pub. L. 101–647, §2003, inserted '', by public sale or any other commercially feasible means,'' after ''sell''.

Subsec. (f). Pub. L. 101–647, §2004, inserted ''; all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2) of this section; and any equipment or container subject to forfeiture under subsection (a)(2) or (3) of this section which cannot be separated safely from such raw materials or products'' after ''this subchapter'' in pars. (1) and (2).

1989—Subsec. (e)(3)(B). Pub. L. 101–189 amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ''is not so transferred to circumvent any requirement of State law that prohibits forfeiture or limits use or disposition of property forfeited to State or local agencies.''

1988—Subsec. (a)(3). Pub. L. 100–690, §6059(b), inserted reference to par. (9).

Subsec. (a)(4). Pub. L. 100–690, §§6059(b), 6075, inserted in introductory provisions reference to par. (9) and added subpar. (C).

Subsec. (a)(7). Pub. L. 100–690, §5105, inserted ''(including any leasehold interest)'' after ''interest''.

Subsec. (a)(9). Pub. L. 100–690, §6059(a), added par. (9).

Subsec. (e)(1)(A). Pub. L. 100–690, §6077(b), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''retain the property for official use or transfer the custody or ownership of any forfeited property to any Federal, State, or local agency pursuant to section 1616a of title 19;''.

Subsec. (e)(1)(E). Pub. L. 100–690, §6074, added subpar. (E).

Subsec. (e)(2)(B). Pub. L. 100–690, §6253(b), provided for deposit of moneys and proceeds in Postal Service Fund in cases of forfeitures conducted by Postal Service.

Subsec. (e)(3). Pub. L. 100–690, §6077(a), added par. (3).

Subsec. (*l*). Pub. L. 100–690, §6253(a), added subsec. (*l*).

1986—Subsec. (b). Pub. L. 99–570, §1865(1)–(3), and Pub. L. 99–646, §74(1)–(3), in making identical amendments in introductory provision and par. (4), struck out ''or criminal'' after ''subject to civil'' and inserted paragraph permitting the Government to request issuance of a warrant authorizing seizure of property subject to forfeiture under this section in the same manner as provided for a search warrant under the Federal Rules of Criminal Procedure.

Subsec. (e). Pub. L. 99–570, §1992, designated existing provisions as par. (1) and former pars. (1) to (4) as subpars. (A) to (D), respectively, and added par. (2) in lieu of former concluding provisions which read as follows: ''The Attorney General shall ensure the equitable transfer pursuant to paragraph (1) of any forfeited property to the appropriate State or local law enforcement agency so as to reflect generally the contribution of any such agency participating directly in any of the acts which led to the seizure or forfeiture of such property. A decision by the Attorney General pursuant to paragraph (1) shall not be subject to review. The proceeds from any sale under paragraph (2) and any moneys forfeited under this subchapter shall be used to pay all proper expenses of the proceedings for forfeiture and sale including expenses of seizure, maintenance of custody, advertising, and court costs. The Attorney General shall forward to the Treasurer of the United States for deposit in accordance with section 524(c) of title 28 any amounts of such moneys and proceeds remaining after payment of such expenses.''

Subsec. (f). Pub. L. 99–570, §1006(c), which directed the amendment of section 511 of the ''Comprehensive Drug Abuse Prevention Act of 1978'' was executed to this section which is section 511 of the Comprehensive Drug Abuse Prevention Act of 1970, as the probable intent of Congress, by designating existing provisions as par. (1), inserting ''or II'' in two places, and adding par. (2).

Subsec. (i). Pub. L. 99–570, §1865(b) and Pub. L. 99–646, §74(b), made identical amendments, inserting '', or a violation of State or local law that could have been charged under this subchapter or subchapter II of this chapter,''.

1984—Subsec. (a)(7). Pub. L. 98–473, §306(a), added par. (7).

Subsec. (a)(8). Pub. L. 98–473, §518, added par. (8).

Subsec. (b). Pub. L. 98–473, §306(b)(1), inserted ''civil or criminal'' after ''property subject to''.

Subsec. (b)(4). Pub. L. 98–473, §306(b)(2), substituted ''is subject to civil or criminal forfeiture under'' for ''has been used or is intended to be used in violation of''.

Subsec. (c). Pub. L. 98–473, §306(c)(1), in provisions preceding par. (1), inserted ''any of'' after ''seized under''.

Subsec. (c)(3). Pub. L. 98–473, §306(c)(2), inserted '', if practicable,'' after ''remove it''.

Subsec. (d). Pub. L. 98–473, §306(d), inserted ''any of'' after ''incurred, under''.

Subsec. (e). Pub. L. 98–473, §§306(e), 309, inserted ''civilly or criminally'' after ''Whenever property is'' and in provisions preceding par. (1), inserted provisions relating to transfer of custody or ownership of forfeited property in par. (1), substituted ''and dispose of it'' for ''and remove it for disposition'' in par. (3), and, in provisions following par. (4), inserted sentence requiring the Attorney General to ensure equitable transfer of any forfeited property, and substituted ''accordance with section 524(c) of title 28'' for ''the general fund of the United States Treasury''.

Subsecs. (h) to (j). Pub. L. 98–473, §306(f), added subsecs. (h) to (j).

1979—Subsec. (d). Pub. L. 96–132 substituted ''The provisions'' for ''All provisions'' and struck out ''and the award of compensation to informers in respect of such forfeitures'' after ''compromise of claims''.

1978—Subsec. (a)(6). Pub. L. 95–633, §301(1), added par. (6).

Subsec. (e). Pub. L. 95–633, §301(a)(2), (3), struck out of cl. (2) provisions relating to use of proceeds of sale and inserted last sentence relating to the forwarding by the Attorney General of money and proceeds remaining after payment of expenses.

EFFECTIVE DATE OF 1989 AMENDMENT

Section 1215(b) of Pub. L. 101–189 provided that: ''The amendment made by subsection (a) [amending this section] shall take effect as of October 1, 1989.''

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by section 6059 of Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

Section 6077(c) of Pub. L. 100–690, as amended by Pub. L. 101–162, title II, § 208, Nov. 21, 1989, 103 Stat. 1005, provided that: ''Section 551(e)(3)(B) of the Controlled Substances Act [probably means section 511(e)(3)(B) of the Controlled Substances Act, 21 U.S.C. 881(e)(3)(B)], as enacted by subsection (a), shall apply with respect to fiscal years beginning after September 30, 1991.''

TRANSFER OF FUNCTIONS

Bureau of Narcotics and Dangerous Drugs, including office of Director thereof, in Department of Justice abolished by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 2 of 1973 also created in Department of Justice a single, comprehensive agency for enforcement of drug laws to be known as Drug Enforcement Administration, empowered Attorney General to authorize performance by officers, employees, and agencies of Department of functions transferred to him, and directed Attorney General to coordinate all drug law enforcement functions to assure maximum cooperation between Drug Enforcement Administration, Federal Bureau of Investigation, and other units of Department of Justice involved in drug law enforcement.

CONSTRUCTIVE SEIZURE PROCEDURES

Pub. L. 101–225, title II, § 210, Dec. 12, 1989, 103 Stat. 1913, provided that: ''Not later than 6 months after the date of enactment of this Act [Dec. 12, 1989], the Secretary of Transportation and the Secretary of the Treasury, in order to avoid the devastating economic effects on innocent owners of seizures of their vessels, shall develop a procedure for constructive seizure of vessels of the United States engaged in commercial service as defined in section 2101 of title 46, United States Code, that are suspected of being used for committing violations of law involving personal use quantities of controlled substances.''

REGULATIONS FOR EXPEDITED ADMINISTRATIVE FORFEITURE PROCEDURES

Section 6079 of Pub. L. 100–690 provided that:

''(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act [Nov. 18, 1988], the Attorney General and the Secretary of the Treasury shall consult, and after providing a 30-day public comment period, shall prescribe regulations for expedited administrative procedures for seizures under section 511(a)(4), (6), and (7) of the Controlled Substances Act (21 U.S.C. 881(a)(4), (6), and (7)); section 596 of the Tariff Act of 1930 (19 U.S.C. 1595a(a)); and section 2 of the Act of August 9, 1939 (53 Stat. 1291; 49 U.S.C. App. 782 [now 49 U.S.C. 80303]) for violations involving the possession of personal use quantities of a controlled substance.

''(b) SPECIFICATIONS.—The regulations prescribed pursuant to subsection (a) shall—

''(1) minimize the adverse impact caused by prolonged detention, and

''(2) provide for a final administrative determination of the case within 21 days of seizure, or provide a procedure by which the defendant can obtain release of the property pending a final determination of the case. Such regulations shall provide that the appropriate agency official rendering a final determination shall immediately return the property if the following conditions are established:

''(A) the owner or interested party did not know of or consent to the violation;

''(B) the owner establishes a valid, good faith interest in the seized property as owner or otherwise; and

''(C)(1) the owner establishes that the owner at no time had any knowledge or reason to believe that the property in which the owner claims an interest was being or would be used in a violation of the law; and

''(2) if the owner at any time had, or should have had, knowledge or reason to believe that the property in which the owner claims an interest was being or would be used in a violation of the law, that the owner did what reasonably could be expected to prevent the violation.

An owner shall not have the seized property returned under this subsection if the owner had not acted in a normal and customary manner to ascertain how the property would be used.

''(c) NOTICE.—At the time of seizure or upon issuance of a summons to appear under subsection (d), the officer making the seizure shall furnish to any person in possession of the conveyance a written notice specifying the procedures under this section. At the earliest practicable opportunity after determining ownership of the seized conveyance, the head of the department or agency that seizes the conveyance shall furnish a written notice to the owner and other interested parties (including lienholders) of the legal and factual basis of the seizure.

''(d) SUMMONS IN LIEU OF SEIZURE OF COMMERCIAL FISHING INDUSTRY VESSELS.—Not later than 90 days after the enactment of this Act [Nov. 18, 1988], the Attorney General, the Secretary of the Treasury, and the Secretary of Transportation shall prescribe joint regulations, after a public comment period of at least 30 days, providing for issuance of a summons to appear in lieu of seizure of a commercial fishing industry vessel as defined in section 2101(11a), (11b), and (11c) of title 46, United States Code, for violations involving the possession of personal use quantities of a controlled substance. These regulations shall apply when the violation is committed on a commercial fishing industry vessel that is proceeding to or from a fishing area or intermediate port of call, or is actively engaged in fishing operations. The authority provided under this section shall not affect existing authority to arrest an individual for drug-related offenses or to release that individual into the custody of the vessel's master. Upon answering a summons to appear, the procedures set forth in subsections (a), (b), and (c) of this section shall apply. The jurisdiction of the district court for any forfeiture incurred shall not be affected by the use of a summons under this section.

''(e) PERSONAL USE QUANTITIES OF A CONTROLLED SUBSTANCE.—For the purposes of this section, personal use quantities of a controlled substance shall not include sweepings or other evidence of non-personal use amounts.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 824, 842, 853, 958, 965 of this title; title 16 section 559d; title 33 section 1415; title 46 App. section 1904.

## §§ 881–1, 881a. Transferred

CODIFICATION

Section 881–1, Pub. L. 91–513, title II, § 511A, as added Pub. L. 100–690, title VI, § 6080(a), Nov. 18, 1988, 102 Stat. 4326, which related to expedited procedures for seized conveyances, was renumbered § 518 of Pub. L. 91–513 by Pub. L. 101–647, title X, § 1002(h)(1), Nov. 29, 1990, 104 Stat. 4828, and transferred to section 888 of this title.

Section 881a, Pub. L. 99–198, title XVII, § 1764, Dec. 23, 1985, 99 Stat. 1652, which related to production control of controlled substances, was renumbered section 519 of the Controlled Substances Act by Pub. L. 101–647, title X, § 1002(h)(2), Nov. 29, 1990, 104 Stat. 4828, and is classified to section 889 of this title.

## § 882. Injunctions

### (a) Jurisdiction

The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this subchapter.

**(b) Jury trial**

In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

(Pub. L. 91–513, title II, § 512, Oct. 27, 1970, 84 Stat. 1278.)

REFERENCES IN TEXT

The Federal Rules of Civil Procedure, referred to in subsecs. (a) and (b), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

**§ 883. Enforcement proceedings**

Before any violation of this subchapter is reported by the Administrator of the Drug Enforcement Administration to any United States attorney for institution of a criminal proceeding, the Administrator may require that the person against whom such proceeding is contemplated is given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

(Pub. L. 91–513, title II, § 513, Oct. 27, 1970, 84 Stat. 1278; Pub. L. 96–132, § 16(c), Nov. 30, 1979, 93 Stat. 1049.)

AMENDMENTS

1979—Pub. L. 96–132 substituted ''Administrator of the Drug Enforcement Administration'' for ''Director of the Bureau of Narcotics and Dangerous Drugs'' and ''Administrator may'' for ''Director may''.

**§ 884. Immunity and privilege**

**(a) Refusal to testify**

Whenever a witness refuses, on the basis of his privilege against self-incrimination, to testify or provide other information in a proceeding before a court or grand jury of the United States, involving a violation of this subchapter, and the person presiding over the proceeding communicates to the witness an order issued under this section, the witness may not refuse to comply with the order on the basis of his privilege against self-incrimination. But no testimony or other information compelled under the order issued under subsection (b) of this section or any information obtained by the exploitation of such testimony or other information, may be used against the witness in any criminal case, including any criminal case brought in a court of a State, except a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order.

**(b) Order of United States district court**

In the case of any individual who has been or may be called to testify or provide other information at any proceeding before a court or grand jury of the United States, the United States district court for the judicial district in which the proceeding is or may be held shall issue, upon the request of the United States attorney for such district, an order requiring such individual to give any testimony or provide any other information which he refuses to give or provide on the basis of his privilege against self-incrimination.

**(c) Request by United States attorney**

A United States attorney may, with the approval of the Attorney General or the Deputy Attorney General, the Associate Attorney General, or any Assistant Attorney General designated by the Attorney General, request an order under subsection (b) of this section when in his judgment—

(1) the testimony or other information from such individual may be necessary to the public interest; and

(2) such individual has refused or is likely to refuse to testify or provide other information on the basis of his privilege against self-incrimination.

(Pub. L. 91–513, title II, § 514, Oct. 27, 1970, 84 Stat. 1278; Pub. L. 100–690, title VII, § 7020(f), Nov. 18, 1988, 102 Stat. 4396.)

AMENDMENTS

1988—Subsec. (c). Pub. L. 100–690 inserted reference to Associate Attorney General.

**§ 885. Burden of proof; liabilities**

**(a) Exemptions and exceptions; presumption in simple possession offenses**

(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

(2) In the case of a person charged under section 844(a) of this title with the possession of a controlled substance, any label identifying such substance for purposes of section 353(b)(2) of this title shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

**(b) Registration and order forms**

In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this subchapter, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

**(c) Use of vehicles, vessels, and aircraft**

The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this subchapter shall be on the persons engaged in such use.

**(d) Immunity of Federal, State, local and other officials**

Except as provided in section 2234 and 2235 of title 18, no civil or criminal liability shall be imposed by virtue of this subchapter upon any duly authorized Federal officer lawfully engaged in the enforcement of this subchapter, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District

of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

(Pub. L. 91–513, title II, § 515, Oct. 27, 1970, 84 Stat. 1279.)

REFERENCES IN TEXT

Schedule I, referred to in subsec. (c), is referred to in section 812(c) of this title.

### § 886. Payments and advances

**(a) Payment to informers**

The Attorney General is authorized to pay any person, from funds appropriated for the Drug Enforcement Administration, for information concerning a violation of this subchapter, such sum or sums of money as he may deem appropriate, without reference to any moieties or rewards to which such person may otherwise be entitled by law.

**(b) Reimbursement for purchase of controlled substances**

Moneys expended from appropriations of the Drug Enforcement Administration for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Administration.[1]

**(c) Advance of funds for enforcement purposes**

The Attorney General is authorized to direct the advance of funds by the Treasury Department in connection with the enforcement of this subchapter.

**(d) Drug Pollution Fund**

(1) There is established in the Treasury a trust fund to be known as the ''Drug Pollution Fund'' (hereinafter referred to in this subsection as the ''Fund''), consisting of amounts appropriated or credited to such Fund under section 841(b)(6) of this title.

(2) There are hereby appropriated to the Fund amounts equivalent to the fines imposed under section 841(b)(6) of this title.

(3) Amounts in the Fund shall be available, as provided in appropriations Acts, for the purpose of making payments in accordance with paragraph (4) for the clean up of certain pollution resulting from the actions referred to in section 841(b)(6) of this title.

(4)(A) The Secretary of the Treasury, after consultation with the Attorney General, shall make payments under paragraph (3), in such amounts as the Secretary determines appropriate, to the heads of executive agencies or departments that meet the requirements of subparagraph (B).

(B) In order to receive a payment under paragraph (3), the head of an executive agency or department shall submit an application in such form and containing such information as the Secretary of the Treasury shall by regulation require. Such application shall contain a description of the fine imposed under section 841(b)(6) of this title, the circumstances surrounding the imposition of such fine, and the type and severity of pollution that resulted from the actions to which such fine applies.

(5) For purposes of subchapter B of chapter 98 of title 26, the Fund established under this paragraph shall be treated in the same manner as a trust fund established under subchapter A of such chapter.

(Pub. L. 91–513, title II, § 516, Oct. 27, 1970, 84 Stat. 1279; Pub. L. 96–132, § 16(b), Nov. 30, 1979, 93 Stat. 1049; Pub. L. 100–690, title VI, § 6254(i), Nov. 18, 1988, 102 Stat. 4367.)

CODIFICATION

In subsec. (b), ''Administration'' substituted for ''Bureau'' as the probable intent of Congress in view of amendment by Pub. L. 96–132, which substituted references to the Drug Enforcement Administration for references to the Bureau of Narcotics and Dangerous Drugs wherever appearing in text.

AMENDMENTS

1988—Subsec. (d). Pub. L. 100–690 added subsec. (d).

1979—Subsecs. (a), (b). Pub. L. 96–132 substituted ''Drug Enforcement Administration'' for ''Bureau of Narcotics and Dangerous Drugs''.

### § 886a. Diversion Control Fee Account

There is established in the general fund of the Treasury a separate account which shall be known as the Diversion Control Fee Account. For fiscal year 1993 and thereafter:

(1) There shall be deposited as offsetting receipts into that account all fees collected by the Drug Enforcement Administration, in excess of $15,000,000, for the operation of its diversion control program.

(2) Such amounts as are deposited into the Diversion Control Fee Account shall remain available until expended and shall be refunded out of that account by the Secretary of the Treasury, at least on a quarterly basis, to reimburse the Drug Enforcement Administration for expenses incurred in the operation of the diversion control program.

(3) Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.

(4) The amount required to be refunded from the Diversion Control Fee Account for fiscal year 1994 and thereafter shall be refunded in accordance with estimates made in the budget request of the Attorney General for those fiscal years. Any proposed changes in the amounts designated in said budget requests shall only be made after notification to the Committees on Appropriations of the House of Representatives and the Senate fifteen days in advance.

(5) The Attorney General shall prepare and submit annually to the Congress, statements of financial condition of the account, including the beginning balance, receipts, refunds to appropriations, transfers to the general fund, and the ending balance.

(Pub. L. 102–395, title I, § 111(b), Oct. 6, 1992, 106 Stat. 1843.)

CODIFICATION

Section was enacted as part of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1993, and not as

[1] See Codification note below.

part of the Controlled Substances Act which comprises this subchapter.

### § 887. Coordination and consolidation of post-seizure administration

The Attorney General and the Secretary of the Treasury shall take such action as may be necessary to develop and maintain a joint plan to coordinate and consolidate post-seizure administration of property seized under this subchapter, subchapter II of this chapter, or provisions of the customs laws relating to controlled substances.

(Pub. L. 91–513, title II, § 517, as added Pub. L. 100–690, title VI, § 6078(a), Nov. 18, 1988, 102 Stat. 4325.)

REFERENCES IN TEXT

The customs laws, referred to in text, are classified generally to Title 19, Customs Duties.

### § 888. Expedited procedures for seized conveyances

**(a) Petition for expedited decision; determination**

(1) The owner of a conveyance may petition the Attorney General for an expedited decision with respect to the conveyance, if the conveyance is seized for a drug-related offense and the owner has filed the requisite claim and cost bond in the manner provided in section 1608 of title 19. The Attorney General shall make a determination on a petition under this section expeditiously, including a determination of any rights or defenses available to the petitioner. If the Attorney General does not grant or deny a petition under this section within 20 days after the date on which the petition is filed, the conveyance shall be returned to the owner pending further forfeiture proceedings.

(2) With respect to a petition under this section, the Attorney General may—

(A) deny the petition and retain possession of the conveyance;

(B) grant the petition, move to dismiss the forfeiture action, if filed, and promptly release the conveyance to the owner; or

(C) advise the petitioner that there is not adequate information available to determine the petition and promptly release the conveyance to the owner.

(3) Release of a conveyance under subsection (a)(1) or (a)(2)(C) of this section does not affect any forfeiture action with respect to the conveyance.

(4) The Attorney General shall prescribe regulations to carry out this section.

**(b) Written notice of procedures**

At the time of seizure, the officer making the seizure shall furnish to any person in possession of the conveyance a written notice specifying the procedures under this section. At the earliest practicable opportunity after determining ownership of the seized conveyance, the head of the department or agency that seizes the conveyance shall furnish a written notice to the owner and other interested parties (including lienholders) of the legal and factual basis of the seizure.

**(c) Complaint for forfeiture**

Not later than 60 days after a claim and cost bond have been filed under section 1608 of title 19 regarding a conveyance seized for a drug-related offense, the Attorney General shall file a complaint for forfeiture in the appropriate district court, except that the court may extend the period for filing for good cause shown or on agreement of the parties. If the Attorney General does not file a complaint as specified in the preceding sentence, the court shall order the return of the conveyance to the owner and the forfeiture may not take place.

**(d) Bond for release of conveyance**

Any owner of a conveyance seized for a drug-related offense may obtain release of the conveyance by providing security in the form of a bond to the Attorney General in an amount equal to the value of the conveyance unless the Attorney General determines the conveyance should be retained (1) as contraband, (2) as evidence of a violation of law, or (3) because, by reason of design or other characteristic, the conveyance is particularly suited for use in illegal activities.

(Pub. L. 91–513, title II, § 518, formerly § 511A, as added Pub. L. 100–690, title VI, § 6080(a), Nov. 18, 1988, 102 Stat. 4326; renumbered § 518, Pub. L. 101–647, title X, § 1002(h)(1), Nov. 29, 1990, 104 Stat. 4828.)

CODIFICATION

Section was classified to section 881–1 of this title prior to renumbering by Pub. L. 101–647.

AMENDMENTS

1990—Pub. L. 101–647 renumbered section 881–1 of this title as this section.

### § 889. Production control of controlled substances

**(a) Definitions**

As used in this section:

(1) The term ''controlled substance'' has the same meaning given such term in section 802(6) of this title.

(2) The term ''Secretary'' means the Secretary of Agriculture.

(3) The term ''State'' means each of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, American Samoa, the Commonwealth of the Northern Mariana Islands, or the Trust Territory of the Pacific Islands.

**(b) Persons ineligible for Federal agricultural program benefits**

Notwithstanding any other provision of law, following December 23, 1985, any person who is convicted under Federal or State law of planting, cultivation, growing, producing, harvesting, or storing a controlled substance in any crop year shall be ineligible for—

(1) as to any commodity produced during that crop year, and the four succeeding crop years, by such person—

(A) any price support or payment made available under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.), the Commodity Credit

Corporation Charter Act (15 U.S.C. 714 et seq.), or any other Act;

(B) a farm storage facility loan made under section 4(h) of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b(h));

(C) crop insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.);

(D) a disaster payment made under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.); or

(E) a loan made, insured or guaranteed under the Consolidated Farm and Rural Development Act (7 U.S.C. 1921 et seq.) or any other provision of law administered by the Farmers Home Administration; or

(2) a payment made under section 4 or 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b or 714c) for the storage of an agricultural commodity that is—

(A) produced during that crop year, or any of the four succeeding crop years, by such person; and

(B) acquired by the Commodity Credit Corporation.

**(c) Regulations**

Not later than 180 days after December 23, 1985, the Secretary shall issue such regulations as the Secretary determines are necessary to carry out this section, including regulations that—

(1) define the term ''person'';

(2) govern the determination of persons who shall be ineligible for program benefits under this section; and

(3) protect the interests of tenants and sharecroppers.

(Pub. L. 91–513, title II, § 519, formerly Pub. L. 99–198, title XVII, § 1764, Dec. 23, 1985, 99 Stat. 1652; renumbered § 519 of Pub. L. 91–513, Pub. L. 101–647, title X, § 1002(h)(2), Nov. 29, 1990, 104 Stat. 4828.)

REFERENCES IN TEXT

The Agricultural Act of 1949, referred to in subsec. (b)(1)(A), (D), is act Oct. 31, 1949, ch. 792, 63 Stat. 1051, as amended, which is classified principally to chapter 35A (§ 1421 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 1421 of Title 7 and Tables.

The Commodity Credit Corporation Charter Act, referred to in subsec. (b)(1)(A), is act June 29, 1948, ch. 704, 62 Stat. 1070, as amended, and is classified generally to subchapter II (§ 714 et seq.) of chapter 15 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 714 of Title 15 and Tables.

The Federal Crop Insurance Act, referred to in subsec. (b)(1)(C), is title V of act Feb. 16, 1938, ch. 30, 52 Stat. 72, as amended, which is classified generally to chapter 36 (§ 1501 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see section 1501 of Title 7 and Tables.

The Consolidated Farm and Rural Development Act, referred to in subsec. (b)(1)(E), is title III of Pub. L. 87–128, Aug. 8, 1961, 75 Stat. 307, as amended, which is classified principally to chapter 50 (§ 1921 et seq.) of Title 7. For complete classification of this Act to the Code, see Short Title note set out under section 1921 of Title 7 and Tables.

CODIFICATION

Section was classified to section 881a of this title prior to renumbering by Pub. L. 101–647.

AMENDMENTS

1990—Pub. L. 101–647 renumbered section 881a of this title as this section.

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

## PART F—GENERAL PROVISIONS

CODIFICATION

The letter designation for this Part F was, in the original, Part G. The original Part F of title II of Pub. L. 91–513, consisting of section 601 thereof, is set out as a note under section 801 of this title. The original Part G of title II of Pub. L. 91–513 consisted of sections 701 to 709. Sections 701 to 705 amended and repealed sections in this title and in Title 18, Crimes and Criminal Procedure, and Title 42, The Public Health and Welfare, and enacted provisions set out as notes under sections 321, 801, and 822 of this title. See Tables for classifications of said sections 701 to 705. Sections 706 to 709 of Pub. L. 91–513 are set out as sections 901 to 904 of this title and, for purposes of codification, comprise this Part F.

### § 901. Severability

If a provision of this chapter is held invalid, all valid provisions that are severable shall remain in effect. If a provision of this chapter is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

(Pub. L. 91–513, title II, § 706, Oct. 27, 1970, 84 Stat. 1284.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original ''this Act'', meaning Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236, as amended. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

### § 902. Savings provisions

Nothing in this chapter, except this part and, to the extent of any inconsistency, sections 827(e) and 829 of this title, shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 301 et seq.].

(Pub. L. 91–513, title II, § 707, Oct. 27, 1970, 84 Stat. 1284.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

### § 903. Application of State law

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this sub-

chapter and that State law so that the two cannot consistently stand together.

(Pub. L. 91–513, title II, §708, Oct. 27, 1970, 84 Stat. 1284.)

REFERENCES IN TEXT

This subchapter, referred to in text, was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

### §904. Payment of tort claims

Notwithstanding section 2680(k) of title 28, the Attorney General, in carrying out the functions of the Department of Justice under this subchapter, is authorized to pay tort claims in the manner authorized by section 2672 of title 28, when such claims arise in a foreign country in connection with the operations of the Drug Enforcement Administration abroad.

(Pub. L. 91–513, title II, §709, Oct. 27, 1970, 84 Stat. 1284; Pub. L. 93–481, §1, Oct. 26, 1974, 88 Stat. 1455; Pub. L. 95–137, §1(a), Oct. 18, 1977, 91 Stat. 1169; Pub. L. 96–132, §§13, 15, Nov. 30, 1979, 93 Stat. 1048; Pub. L. 97–414, §9(g)(1), Jan. 4, 1983, 96 Stat. 2064.)

AMENDMENTS

1983—Pub. L. 97–414 struck out subsecs. (a) and (b) which had provided, respectively, that (a) there were authorized to be appropriated $105,000,000 for the fiscal year ending June 30, 1975, $175,000,000 for the fiscal year ending June 30, 1976, $200,000,000 for the fiscal year ending September 30, 1977, $188,000,000 for the fiscal year ending September 30, 1978, $215,000,000 for the fiscal year ending September 30, 1979, and $198,336,000 for the fiscal year ending September 30, 1980, for the expenses of the Department of Justice in carrying out its functions under this subchapter, and that (b) no funds appropriated under any other provision of this chapter could be used for the expenses of the Department of Justice for which funds were authorized to be appropriated by former subsection (a) of this section, and removed the subsection designator (c) before ''Notwithstanding''.

1979—Subsec. (a). Pub. L. 96–132, §15, inserted provisions authorizing appropriations of $198,336,000 for the fiscal year ending Sept. 30, 1980.

Subsec. (c). Pub. L. 96–132, §13, added subsec. (c).

1977—Subsec. (a). Pub. L. 95–137 substituted ''September 30, 1977, $188,000,000 for the fiscal year ending September 30, 1978, and $215,000,000 for the fiscal year ending September 30, 1979,'' for ''June 30, 1977,'' and struck out ''(other than its expenses incurred in connection with carrying out section 803(a) of this title)''.

1974—Pub. L. 93–481 designated existing provisions as subsec. (a), substituted authorization of appropriations for fiscal years ending June 30, 1975, June 30, 1976, and June 30, 1977, for authorization of appropriations for fiscal years ending June 30, 1972, June 30, 1973, and June 30, 1974, and added subsec. (b).

## SUBCHAPTER II—IMPORT AND EXPORT

CODIFICATION

This subchapter is comprised of Part A of title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285. Part B of title III contains amendatory, repealing, and transitional provisions generally classified elsewhere.

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 381, 802, 824, 828, 830, 841, 842, 843, 844, 848, 849, 850, 853, 854, 861, 881, 887 of this title; title 10 section 374; title 12 section 3420; title 18 sections 924, 929, 3142, 3554, 3592; title 19 section 1401; title 22 section 2714; title 28 section 524; title 42 section 242; title 48 section 1494b.

### §951. Definitions

(a) For purposes of this subchapter—

(1) The term ''import'' means, with respect to any article, any bringing in or introduction of such article into any area (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(2) The term ''customs territory of the United States'' has the meaning assigned to such term by general note 2 of the Harmonized Tariff Schedule of the United States.

(b) Each term defined in section 802 of this title shall have the same meaning for purposes of this subchapter as such term has for purposes of subchapter I of this chapter.

(Pub. L. 91–513, title III, §1001, Oct. 27, 1970, 84 Stat. 1285; Pub. L. 100–418, title I, §1214(m), Aug. 23, 1988, 102 Stat. 1158.)

REFERENCES IN TEXT

The Harmonized Tariff Schedule of the United States, referred to in subsec. (a)(2), is not set out in the Code. See Publication of Harmonized Tariff Schedule note set out under section 1202 of Title 19, Customs Duties.

This subchapter, referred to in subsecs. (a) and (b), was in the original ''this title'', meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, as amended. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

1988—Subsec. (a)(2). Pub. L. 100–418 substituted ''general note 2 of the Harmonized Tariff Schedule of the United States'' for ''general headnote 2 to the Tariff Schedules of the United States''.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–418 effective Jan. 1, 1989, and applicable with respect to articles entered on or after such date, see section 1217(b)(1) of Pub. L. 100–418, set out as an Effective Date note under section 3001 of Title 19, Customs Duties.

EFFECTIVE DATE

Section 1105(a)–(c) of title III of Pub. L. 91–513, as amended by Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095, provided that:

''(a) Except as otherwise provided in this section, this title [see Short Title note below] shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment [Oct. 27, 1970].

''(b) Sections 1000, 1001, 1006, 1015, 1016, 1103, 1104 [see Short Title note below and sections 171 note, 951, 956, 957 note, 965, and 966 of this title], and this section shall become effective upon enactment [Oct. 27, 1970].

''(c)(1) If the Attorney General, pursuant to the authority of section 704(c) of title II [set out as a note under section 801 of this title], postpones the effective date of section 306 (relating to manufacturing quotas) [section 826 of this title] for any period beyond the date specified in section 704(a) [set out as a note under section 801 of this title], and such postponement applies to narcotic drugs, the repeal of the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title] by paragraph (10) of section 1101(a) of this title is hereby postponed for the same period, except that the postponement made by this paragraph shall not apply to the re-

peal of sections 4, 5, 13, 15, and 16 of that Act [which were classified to sections 182, 503, 511, and 513 of this title and sections 4702, 4731, and 4731 note of Title 26, Internal Revenue Code].

''(2) Effective for any period of postponement, by paragraph (1) of this subsection, of the repeal of provisions of the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title], that Act shall be applied subject to the following modifications:

''(A) The term 'narcotic drug' shall mean a narcotic drug as defined in section 102(16) of title II [section 802(16) of this title], and all references, in the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title], to a narcotic drug as defined by section 4731 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4731 of Title 26] are amended to refer to a narcotic drug as defined by such section 102(16) [section 802(16) of this title].

''(B) On and after the date prescribed by the Attorney General pursuant to clause (2) of section 703(c) of title II, [set out as a note under section 822 of this title], the requirements of a manufacturer's license with respect to a basic class of narcotic drug under the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title], and of a registration under section 4722 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4722 of Title 26] as a prerequisite to issuance of such a license, shall be superseded by a requirement of actual registration (as distinguished from provisional registration) as a manufacturer of that class of drug under section 303(a) of title II [section 823(a) of this title].

''(C) On and after the effective date of the repeal of such section 4722 [section 4722 of title 26] by section 1101(b)(3) of this title, but prior to the date specified in subparagraph (B) of this paragraph, the requirement of registration under such section 4722 [section 4722 of title 26] as a prerequisite of a manufacturer's license under the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title] shall be superseded by a requirement of either (i) actual registration as a manufacturer under section 303 of title II [section 823 of this title] or (ii) provisional registration (by virtue of a preexisting registration under such section 4722) under section 703 of title II [set out as a note under section 822 of this title].''

SHORT TITLE

Section 1000 of title III of Pub. L. 91–513 provided that: ''This title [enacting this subchapter, amending sections 162 and 967 of this title, section 4251 of Title 18, Crimes and Criminal Procedure, section 1584 of Title 19, Customs Duties, sections 4901, 4905, 6808, 7012, 7103, 7326, 7607, 7609, 7641, 7651, and 7655 of Title 26, Internal Revenue Code, section 2901 of Title 28, Judiciary and Judicial Procedure, sections 529d, 529e, and 529f of former Title 31, Money and Finance, section 304m of Title 40, Public Buildings, Property, and Works, section 3411 of Title 42, The Public Health and Welfare, section 239a of former Title 46, Shipping, and section 787 of former Title 49, Transportation, repealing sections 171 to 174, 176 to 185, 188 to 188n, 191 to 193, 197, 198, 199, and 501 to 517 of this title, sections 1401 to 1407, and 3616 of Title 18, sections 4701 to 4707, 4711 to 4716, 4721 to 4726, 4731 to 4736, 4741 to 4746, 4751 to 4757, 4761, 4762, 4771 to 4776, 7237, 7238, and 7491 of Title 26, sections 529a and 529g of former Title 31, section 1421m of Title 48, Territories and Insular Possessions, and enacting provisions set out as notes under this section and sections 171 and 957 of this title] may be cited as the 'Controlled Substances Import and Export Act'.''

RULES AND REGULATIONS

Section 1105(d) of Pub. L. 91–513 provided: ''Any orders, rules and regulations which have been promulgated under any law affected by this title [see Short Title note above] and which are in effect on the day preceding enactment of this title [Oct. 27, 1970] shall continue in effect until modified, superseded, or repealed.''

## § 952. Importation of controlled substances

### (a) Controlled substances in schedule I or II and narcotic drugs in schedule III, IV, or V; exceptions

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of subchapter I of this chapter, or any narcotic drug in schedule III, IV, or V of subchapter I of this chapter, except that—

(1) such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and

(2) such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(A) during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate,

(B) in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 823 of this title, or

(C) in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses,

may be so imported under such regulations as the Attorney General shall prescribe. No crude opium may be so imported for the purpose of manufacturing heroin or smoking opium.

### (b) Nonnarcotic controlled substances in schedule III, IV, or V

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V, unless such nonnarcotic controlled substance—

(1) is imported for medical, scientific, or other legitimate uses, and

(2) is imported pursuant to such notification, or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe, except that if a nonnarcotic controlled substance in schedule IV or V is also listed in schedule I or II of the Convention on Psychotropic Substances it shall be imported pursuant to such import permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

### (c) Coca leaves

In addition to the amount of coca leaves authorized to be imported into the United States

under subsection (a) of this section, the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

(Pub. L. 91–513, title III, § 1002, Oct. 27, 1970, 84 Stat. 1285; Pub. L. 95–633, title I, § 105, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, §§ 519–521, Oct. 12, 1984, 98 Stat. 2075.)

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a) and (b), are set out in section 812(c) of this title.

AMENDMENTS

1984—Subsec. (a)(1). Pub. L. 98–473, § 519, amended par. (1) generally, inserting references to poppy straw and concentrate of poppy straw.

Subsec. (a)(2)(C). Pub. L. 98–473, § 520, added subpar. (C).

Subsec. (b)(2). Pub. L. 98–473, § 521, substituted ''is imported pursuant to such notification, or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe, except that if a nonnarcotic controlled substance in schedule IV or V is also listed in schedule I or II of the Convention on Psychotropic Substances it shall be imported pursuant to such import permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention'' for ''is imported pursuant to such notification or declaration requirements as the Attorney General may by regulation prescribe, except that if a nonnarcotic controlled substance in schedule III, IV, or V is also listed in schedule I or II of the Convention on Psychotropic Substances it shall be imported pursuant to such import permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention''.

1978—Subsec. (b)(2). Pub. L. 95–633 inserted provision relating to exception for nonnarcotic controlled substances listed in schedule I or II of the Convention on Psychotropic Substances.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 954, 956, 958, 960 of this title; title 18 sections 5032, 5038; title 28 section 994.

## § 953. Exportation of controlled substances

### (a) Narcotic drugs in schedule I, II, III, or IV

It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless—

(1) it is exported to a country which is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925; or

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention on July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948; or

(C) the Single Convention on Narcotic Drugs, 1961, signed at New York, March 30, 1961;

(2) such country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs which the Attorney General deems adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import such drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

### (b) Exception for exportation for special scientific purposes

Notwithstanding subsection (a) of this section, the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country which is a party to any of the international instruments mentioned in subsection (a) of this section if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

### (c) Nonnarcotic controlled substances in schedule I or II

It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has instituted and maintains a system which the Attorney General deems adequate for the control of imports of such substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that (A) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country to which exported, (B) it will not be exported from such country, and (C) there is an actual need for the controlled substance for

medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

**(d) Exception for exportation for special scientific purposes**

Notwithstanding subsection (c) of this section, the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

**(e) Nonnarcotic controlled substances in schedule III or IV; controlled substances in schedule V**

It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substance in schedule III or IV or any controlled substances in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes;

(2) it is exported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such export permit, notification, or declaration as the Attorney General may by regulation prescribe; and

(3) in the case of a nonnarcotic controlled substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substances, it is exported pursuant to such export permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

(Pub. L. 91–513, title III, § 1003, Oct. 27, 1970, 84 Stat. 1286; Pub. L. 95–633, title I, § 106, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, § 522, Oct. 12, 1984, 98 Stat. 2076.)

REFERENCES IN TEXT

Schedules I, II, III, IV and V, referred to in text, are set out in section 812(c) of this title.

AMENDMENTS

1984—Subsec. (e). Pub. L. 98–473 in cl. (1) inserted provisions for consumption for medical, etc., purposes, added cls. (2) and (3), and struck out former cls. (2) to (4), respectively, relating to a special controlled substance invoice, two additional copies of the invoice, and exportation of a nonnarcotic controlled substance in schedule III, IV, or V, also listed in schedule I or II of the Convention.

1978—Subsec. (e)(4). Pub. L. 95–633 added par. (4).

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 954, 956, 960 of this title; title 18 section 5032; title 48 section 1972.

## § 954. Transshipment and in-transit shipment of controlled substances

Notwithstanding sections 952, 953, and 957 of this title—

(1) A controlled substance in schedule I may—

(A) be imported into the United States for transshipment to another country, or

(B) be transferred or transshipped from one vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation,

if and only if it is so imported, transferred, or transshipped (i) for scientific, medical, or other legitimate purposes in the country of destination, and (ii) with the prior written approval of the Attorney General (which shall be granted or denied within 21 days of the request).

(2) A controlled substance in schedule II, III, or IV may be so imported, transferred, or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.

(Pub. L. 91–513, title III, § 1004, Oct. 27, 1970, 84 Stat. 1287.)

REFERENCES IN TEXT

Schedules I, II, III, and IV, referred to in text, are set out in section 812(c) of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 956, 961 of this title.

## § 955. Possession on board vessels, etc., arriving in or departing from United States

It shall be unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier, arriving in or departing from the United States or the customs territory of the United States, a controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless such substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

(Pub. L. 91–513, title III, § 1005, Oct. 27, 1970, 84 Stat. 1287.)

REFERENCES IN TEXT

Schedules I, II, III, and IV, referred to in text, are set out in section 812(c) of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 956, 960 of this title; title 18 sections 5032, 5038; title 28 section 994.

## §§ 955a to 955d. Transferred

CODIFICATION

Sections, Pub. L. 96–350, §§ 1–4, Sept. 15, 1980, 94 Stat. 1159, 1160, relating to maritime drug law enforcement, were transferred to sections 1901 to 1904 of Title 46, Appendix, Shipping.

## § 956. Exemption authority

**(a) Individual possessing controlled substance**

The Attorney General may by regulation exempt from sections 952(a) and (b), 953, 954, and

955 of this title any individual who has a controlled substance (except a substance in schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if he lawfully obtained such substance and he makes such declaration (or gives such other notification) as the Attorney General may by regulation require.

**(b) Compound, mixture, or preparation**

The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance listed in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this subchapter if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

(Pub. L. 91–513, title III, §1006, Oct. 27, 1970, 84 Stat. 1288.)

REFERENCES IN TEXT

Schedules I, III, IV, and V, referred to in text, are set out in section 812(c) of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 957 of this title.

## §957. Persons required to register

**(a) Coverage**

No person may—

(1) import into the customs territory of the United States from any place outside thereof (but within the United States), or import into the United States from any place outside thereof, any controlled substance or list I chemical, or

(2) export from the United States any controlled substance or list I chemical,

unless there is in effect with respect to such person a registration issued by the Attorney General under section 958 of this title, or unless such person is exempt from registration under subsection (b) of this section.

**(b) Exemptions**

(1) The following persons shall not be required to register under the provisions of this section and may lawfully possess a controlled substance or list I chemical:

(A) An agent or an employee of any importer or exporter registered under section 958 of this title if such agent or employee is acting in the usual course of his business or employment.

(B) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance or list I chemical is in the usual course of his business or employment.

(C) An ultimate user who possesses such substance for a purpose specified in section 802(25)[1] of this title and in conformity with an exemption granted under section 956(a) of this title.

(2) The Attorney General may, by regulation, waive the requirement for registration of certain importers and exporters if he finds it consistent with the public health and safety; and may authorize any such importer or exporter to possess controlled substances or list I chemicals for purposes of importation and exportation.

(Pub. L. 91–513, title III, §1007, Oct. 27, 1970, 84 Stat. 1288; Pub. L. 98–473, title II, §523, Oct. 12, 1984, 98 Stat. 2076; Pub. L. 103–200, §3(e), Dec. 17, 1993, 107 Stat. 2337.)

REFERENCES IN TEXT

Section 802(25) of this title, referred to in subsec. (b)(1)(C), was redesignated section 802(26) of this title by Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071, and was further redesignated section 802(27) of this title by Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–200, §3(e)(1)(A), inserted ''or list I chemical'' after ''controlled substance''.

Subsec. (a)(2). Pub. L. 103–200, §3(e)(1)(B), substituted ''or list I chemical,'' for ''in schedule I, II, III, IV, or V,''.

Subsec. (b)(1). Pub. L. 103–200, §3(e)(2)(A), inserted ''or list I chemical'' after ''controlled substance'' in introductory provisions and subpar. (B).

Subsec. (b)(2). Pub. L. 103–200, §3(e)(2)(B), inserted ''or list I chemicals'' after ''controlled substances''.

1984—Subsec. (a)(2). Pub. L. 98–473 inserted reference to schedule V.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

PROVISIONAL REGISTRATION

Section 1104 of Pub. L. 91–513, as amended by Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095, provided that:

''(a)(1) Any person—

''(A) who is engaged in importing or exporting any controlled substance on the day before the effective date of section 1007 [May 1, 1971],

''(B) who notifies the Attorney General that he is so engaged, and

''(C) who is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4722 of title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 1008 [section 958 of this title] for the import or export (as the case may be) of controlled substances.

''(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of part A of this title [this subchapter].

''(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

''(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

''(1) the date on which such person has registered with the Attorney General under section 1008 [section

[1] See References in Text note below.

958 of this title] or has had his registration denied under such section, or

''(2) such date as may be prescribed by the Attorney General for registration of importers or exporters, as the case may be,

whichever occurs first.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 954, 960, 965 of this title.

### § 958. Registration requirements

#### (a) Applicants to import or export controlled substances in schedule I or II

The Attorney General shall register an applicant to import or export a controlled substance in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 823(a) of this title shall be considered.

#### (b) Activity limited to specified substances

Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration.

#### (c) Applicants to import controlled substances in schedule III, IV, or V or to export controlled substances in schedule III or IV; applicants to import or export list I chemicals

(1) The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 823(d) of this title shall be considered.

(2)(A) The Attorney General shall register an applicant to import or export a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the import or export of a drug product that is exempted under section 802(39)(A)(iv) of this title.

(B) In determining the public interest for the purposes of subparagraph (A), the Attorney General shall consider the factors specified in section 823(h) of this title.

#### (d) Denial of application

(1) The Attorney General may deny an application for registration under subsection (a) of this section if he is unable to determine that such registration is consistent with the public interest (as defined in subsection (a) of this section) and with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

(2) The Attorney General may deny an application for registration under subsection (c) of this section, or revoke or suspend a registration under subsection (a) or (c) of this section, if he determines that such registration is inconsistent with the public interest (as defined in subsection (a) or (c) of this section) or with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

(3) The Attorney General may limit the revocation or suspension of a registration to the particular controlled substance, or substances, or list I chemical or chemicals, with respect to which grounds for revocation or suspension exist.

(4) Before taking action pursuant to this subsection, the Attorney General shall serve upon the applicant or registrant an order to show cause as to why the registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General, or his designee, at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this subsection in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(5) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this subsection, in cases where he finds that there is an imminent danger to the public health and safety. Such suspension shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(6) In the event that the Attorney General suspends or revokes a registration granted under this section, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be seized or placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded, except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of the sale thereof which have been deposited with the court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title.

#### (e) Registration period

No registration shall be issued under this subchapter for a period in excess of one year. Unless the regulations of the Attorney General otherwise provide, sections 822(f), 825, 827, and 830 of this title shall apply to persons registered under this section to the same extent such sections apply to persons registered under section 823 of this title.

**(f) Rules and regulations**

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration of importers and exporters of controlled substances or list I chemicals under this section.

**(g) Scope of authorized activity**

Persons registered by the Attorney General under this section to import or export controlled substances or list I chemicals may import or export (and for the purpose of so importing or exporting, may possess) such substances to the extent authorized by their registration and in conformity with the other provisions of this subchapter and subchapter I of this chapter.

**(h) Separate registrations for each principal place of business**

A separate registration shall be required at each principal place of business where the applicant imports or exports controlled substances or list I chemicals.

**(i) Emergency situations**

Except in emergency situations as described in section 952(a)(2)(A) of this title, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 952(a) of this title authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

(Pub. L. 91–513, title III, § 1008, Oct. 27, 1970, 84 Stat. 1289; Pub. L. 98–473, title II, §§ 524, 525, Oct. 12, 1984, 98 Stat. 2076; Pub. L. 99–570, title I, § 1866(d), Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 103–200, § 3(f), Dec. 17, 1993, 107 Stat. 2337.)

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a), (c), and (i), are set out in section 812(c) of this title.

This subchapter, referred to in subsecs. (d)(4) and (g), was in the original ''this title'', meaning title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, as amended. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

CODIFICATION

In subsecs. (a) and (d), ''May 1, 1971'' substituted for ''the effective date of this section'' and ''the effective date of this part'', respectively.

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–200, § 3(f)(1), designated existing provisions as par. (1) and added par. (2).

Subsec. (d)(3). Pub. L. 103–200, § 3(f)(2)(A), inserted ''or list I chemical or chemicals,'' after ''substances,''.

Subsec. (d)(6). Pub. L. 103–200, § 3(f)(2)(B), inserted ''or list I chemicals'' after ''controlled substances'' wherever appearing.

Subsec. (e). Pub. L. 103–200, § 3(f)(3), inserted reference to section 830 of this title.

Subsecs. (f) to (h). Pub. L. 103–200, § 3(f)(4), inserted ''or list I chemicals'' after ''controlled substances''.

1986—Subsec. (e). Pub. L. 99–570 substituted ''sections'' for first reference to ''section''.

1984—Subsec. (b). Pub. L. 98–473, § 524, substituted ''Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration'' for ''Registration granted under subsection (a) of this section shall not entitle a registrant to import or export controlled substances in schedule I or II other than those specified in the registration''.

Subsecs. (d) to (i). Pub. L. 98–473, § 525, added subsec. (d), redesignated former subsec. (d) as (e) and struck out reference to section 824 of this title, and redesignated former subsecs. (e) to (h) as (f) to (i), respectively.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 957, 965 of this title.

## § 959. Possession, manufacture, or distribution of controlled substance

**(a) Manufacture or distribution for purpose of unlawful importation**

It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II—

(1) intending that such substance will be unlawfully imported into the United States or into waters within a distance of 12 miles of the coast of the United States; or

(2) knowing that such substance will be unlawfully imported into the United States or into waters within a distance of 12 miles of the coast of the United States.

**(b) Possession, manufacture, or distribution by person on board aircraft**

It shall be unlawful for any United States citizen on board any aircraft, or any person on board an aircraft owned by a United States citizen or registered in the United States, to—

(1) manufacture or distribute a controlled substance; or

(2) possess a controlled substance with intent to distribute.

**(c) Acts committed outside territorial jurisdiction of United States; venue**

This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States. Any person who violates this section shall be tried in the United States district court at the point of entry where such person enters the United States, or in the United States District Court for the District of Columbia.

(Pub. L. 91–513, title III, § 1009, Oct. 27, 1970, 84 Stat. 1289; Pub. L. 99–570, title III, § 3161(a), Oct. 27, 1986, 100 Stat. 3207–94.)

REFERENCES IN TEXT

Schedules I and II, referred to in subsec. (a), are set out in section 812(c) of this title.

AMENDMENTS

1986—Pub. L. 99–570 designated first sentence as subsec. (a) and inserted ''or into waters within a distance of 12 miles of the coast of the United States'' in pars. (1) and (2), added subsec. (b), and designated last two sentences as subsec. (c).

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 960 of this title; title 18 sections 5032, 5038; title 28 section 994.

**§ 960. Prohibited acts A**

**(a) Unlawful acts**

Any person who—

(1) contrary to section 952, 953, or 957 of this title, knowingly or intentionally imports or exports a controlled substance,

(2) contrary to section 955 of this title, knowingly or intentionally brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or

(3) contrary to section 959 of this title, manufactures, possesses with intent to distribute, or distributes a controlled substance,

shall be punished as provided in subsection (b) of this section.

**(b) Penalties**

(1) In the case of a violation of subsection (a) of this section involving—

(A) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(B) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(i) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(ii) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(iii) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(iv) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in clauses (i) through (iii);

(C) 50 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

(D) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(E) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(F) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[ 1-(2-phenylethyl)-4-piperidinyl ] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(G) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 100 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 1 kilogram or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.[1]

the person committing such violation shall be sentenced to a term of imprisonment of not less than 10 years and not more than life and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than 20 years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $8,000,000 if the defendant is an individual or $20,000,000 if the defendant is other than an individual, or both. Any sentence under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this paragraph. No person sentenced under this paragraph shall be eligible for parole during the term of imprisonment imposed therein.

(2) In the case of a violation of subsection (a) of this section involving—

(A) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(B) 500 grams or more of a mixture or substance containing a detectable amount of—

(i) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(ii) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(iii) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(iv) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in clauses (i) through (iii);

(C) 5 grams or more of a mixture or substance described in subparagraph (B) which contains cocaine base;

(D) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(E) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(F) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[ 1-(2-phenylethyl)-4-piperidinyl ] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(G) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(H) 10 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or

[1] So in original. The period probably should be a semicolon.

100 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.[2]

the person committing such violation shall be sentenced to a term of imprisonment of not less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $4,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Any sentence imposed under this paragraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this paragraph. No person sentenced under this paragraph shall be eligible for parole during the term of imprisonment imposed therein.

(3) In the case of a violation under subsection (a) of this section involving a controlled substance in schedule I or II, the person committing such violation shall, except as provided in paragraphs (1), (2), and (4), be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years and not more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding the prior sentence, and notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(4) In the case of a violation under subsection (a) of this section with respect to less than 50 kilograms of marihuana, except in the case of 100 or more marihuana plants regardless of weight, less than 10 kilograms of hashish, less than one kilogram of hashish oil, or any quantity of a controlled substance in schedule III, IV, or V, the person committing such violation shall be imprisoned not more than five years, or be fined not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall, in addition to such term of imprisonment, include (A) a term of supervised release of not less than two years if such controlled substance is in schedule I, II, III, or (B) a term of supervised release of not less than one year if such controlled substance is in schedule IV.

**(c) Repealed. Pub. L. 98–473, title II, §225, formerly §225(a), Oct. 12, 1984, 98 Stat. 2030, as amended by Pub. L. 99–570, title I, §1005(c), Oct. 27, 1986, 100 Stat. 3207–6**

**(d) Penalty for importation or exportation**

A person who knowingly or intentionally—

(1) imports or exports a listed chemical with intent to manufacture a controlled substance in violation of this subchapter or subchapter I of this chapter;

(2) exports a listed chemical in violation of the laws of the country to which the chemical is exported or serves as a broker or trader for an international transaction involving a listed chemical, if the transaction is in violation of the laws of the country to which the chemical is exported;

(3) imports or exports a listed chemical knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of this subchapter or subchapter I of this chapter;

(4) exports a listed chemical, or serves as a broker or trader for an international transaction involving a listed chemical, knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported;

(5) imports or exports a listed chemical, with the intent to evade the reporting or recordkeeping requirements of section 971 of this title applicable to such importation or exportation by falsely representing to the Attorney

[2] So in original. The period probably should be a semicolon.

General that the importation or exportation qualifies for a waiver of the 15-day notification requirement granted pursuant to section 971(e)(2) or (3) of this title by misrepresenting the actual country of final destination of the listed chemical or the actual listed chemical being imported or exported; or

(6) imports or exports a listed chemical in violation of section 957 or 971 of this title,

shall be fined in accordance with title 18, imprisoned not more than 10 years, or both.

(Pub. L. 91–513, title III, § 1010, Oct. 27, 1970, 84 Stat. 1290; Pub. L. 98–473, title II, §§ 225, formerly § 225(a), 504, Oct. 12, 1984, 98 Stat. 2030, 2070; Pub. L. 99–570, title I, §§ 1004(a), 1005(c), 1302, 1866(e), Oct. 27, 1986, 100 Stat. 3207–6, 3207–15, 3207–55; Pub. L. 100–690, title VI, §§ 6053(c), 6475, Nov. 18, 1988, 102 Stat. 4315, 4380; Pub. L. 101–647, title XII, § 1204, title XXXV, § 3599J, Nov. 29, 1990, 104 Stat. 4830, 4932; Pub. L. 103–200, §§ 4(b), 5(b), Dec. 17, 1993, 107 Stat. 2338, 2339; Pub. L. 103–322, title IX, § 90105(a), title XXXIII, § 330024(d)(2), Sept. 13, 1994, 108 Stat. 1987, 2151.)

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsec. (b), are set out in section 812(c) of this title.

AMENDMENTS

1994—Subsec. (b)(1), (2). Pub. L. 103–322, § 90105(a), in sentence in concluding provisions beginning ''If any person commits'', substituted ''a prior conviction for a felony drug offense has become final'' for ''one or more prior convictions for an offense punishable under this subsection, or for a felony under any other provision of this subchapter or subchapter I of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final''.

Subsec. (b)(3). Pub. L. 103–322, § 90105(a), in sentence beginning ''If any person commits'', substituted ''a prior conviction for a felony drug offense has become final'' for ''one or more prior convictions for an offense punishable under this subsection, or for a felony under any other provision of this subchapter or subchapter I of this chapter or other law of a State, the United States or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final''.

Subsec. (d)(5), (6). Pub. L. 103–322, § 330024(d)(2), amended directory language of Pub. L. 103–200, § 5(b)(3). See 1993 Amendment note below.

1993—Subsec. (d). Pub. L. 103–200, § 5(b), as amended by Pub. L. 103–322, § 330024(d)(2), added pars. (5) and (6).

Pub. L. 103–200, § 4(b), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows: ''Any person who knowingly or intentionally—

''(1) imports or exports a listed chemical with intent to manufacture a controlled substance in violation of this subchapter or, in the case of an exportation, in violation of the law of the country to which the chemical is exported; or

''(2) imports or exports a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance in violation of this subchapter or, in the case of an exportation, in violation of the law of the country to which the chemical is exported;

shall be fined in accordance with title 18, or imprisoned not more than 10 years, or both.''

1990—Subsec. (b)(1)(H). Pub. L. 101–647, § 1204(a), added subpar. (H).

Subsec. (b)(2). Pub. L. 101–647, § 3599J, substituted ''supervised'' for ''suspervised'' in two places in concluding provisions.

Subsec. (b)(2)(H). Pub. L. 101–647, § 1204(b), added subpar. (H).

1988—Subsec. (a)(3). Pub. L. 100–690, § 6475, substituted ''manufactures, possesses with intent to distribute, or distributes a controlled substance'' for ''manufactures or distributes a controlled substance''.

Subsec. (d). Pub. L. 100–690, § 6053(c), added subsec. (d).

1986—Pub. L. 99–570, § 1005(c), amended Pub. L. 98–473, § 225. See 1984 Amendment note below.

Subsec. (b)(1), (2). Pub. L. 99–570, § 1302(a)(2), added pars. (1) and (2) and struck out former pars. (1) and (2) which read as follows:

''(1) In the case of a violation under subsection (a) of this section involving—

''(A) 100 grams or more of a mixture or substance containing a detectable amount of a narcotic drug in schedule I or II other than a narcotic drug consisting of—

''(i) coca leaves;

''(ii) a compound, manufacture, salt, derivative, or preparation of coca leaves; or

''(iii) a substance chemically identical thereto;

''(B) a kilogram or more of any other narcotic drug in schedule I or II;

''(C) 500 grams or more of phencyclidine (PCP);

''(D) 5 grams or more of lysergic acid diethylamide (LSD);

the person committing such violation shall be imprisoned for not more than twenty years, or fined not more than $250,000, or both.

''(2) In the case of a violation under subsection (a) of this section with respect to a controlled substance in schedule I or II, the person committing such violation shall, except as provided in paragraphs (1) and (3), be imprisoned not more than fifteen years, or fined not more than $125,000, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall include a special parole term of not less than three years in addition to such term of imprisonment.''

Subsec. (b)(3). Pub. L. 99–570, § 1302(a)(2), added par. (3). Former par. (3) redesignated (4).

Subsec. (b)(4). Pub. L. 99–570, § 1302(a)(1), (3), (b)(2), (3), redesignated former par. (3) as (4), inserted ''except in the case of 100 or more marihuana plants regardless of weight,'' and substituted ''fined not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual'' for ''fined not more than $50,000''.

Pub. L. 99–570, §§ 1302(b)(1), 1866(e), made identical amendment striking out '', except as provided in paragraph (4)'' after ''such violation shall''.

Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term'' in two places.

Subsec. (c). Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term'' wherever appearing, effective Nov. 1, 1987, the effective date of the repeal of subsec. (c) by Pub. L. 98–473, § 225. See 1984 Amendment note below.

1984—Subsec. (b). Pub. L. 98–473, § 225(a), which directed amendment of this subsection effective Nov. 1, 1987 (see section 235(a)(1) of Pub. L. 98–473 set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure) was omitted in the general amendment of section 225 of Pub. L. 98–473 by Pub. L. 99–570, § 1005(c).

Subsec. (b)(1). Pub. L. 98–473, § 504(1), added par. (1). Former par. (1) redesignated (2).

Subsec. (b)(2). Pub. L. 98–473, § 504(1), (2), redesignated former par. (1) as (2), inserted provisions excepting pars. (1) and (3), and substituted reference to controlled substance for reference to narcotic drug, and ''$125,000'' for ''$25,000''. Former par. (2) redesignated (3).

Subsec. (b)(3). Pub. L. 98–473, § 504(1), (3), redesignated former par. (2) as (3) and substituted ''less than 50 kilograms of marihuana, less than 10 kilograms of hashish, less than one kilogram of hashish oil, or any quantity of a controlled substance in schedule III, IV, or V, the person committing such violation shall, except as provided in paragraph (4)'' for ''a controlled substance

other than a narcotic drug in schedule I or II, the person committing such violation shall'', and ''$50,000'' for ''$15,000''.

Subsec. (c). Pub. L. 98–473, § 225, as amended by Pub. L. 99–570, § 1005(c), struck out subsec. (c) which related to special parole terms imposed under this section or section 962 of this title. Notwithstanding directory language that the amendment be made to ''Section 1515 of the Controlled Substances Import and Export Act (21 U.S.C. 960)'', the amendment was executed to this section as the probable intent of Congress.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by section 330024(d)(2) of Pub. L. 103–322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub. L. 103–322, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by section 6053(c) of Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 1004(a) of Pub. L. 99–570 effective on date of taking effect of section 3583 of Title 18, Crimes and Criminal Procedure (Nov. 1, 1987), see section 1004(b) of Pub. L. 99–570 set out as a note under section 841 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 225 of Pub. L. 98–473 effective Nov. 1, 1987, and applicable only to offenses committed after the taking effect of such amendment, see section 235(a)(1) of Pub. L. 98–473, set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 848, 962 of this title; title 18 sections 36, 3553, 3559, 5032; title 28 section 994; title 46 App. section 1903.

## § 961. Prohibited acts B

Any person who violates section 954 of this title or fails to notify the Attorney General of an importation or exportation under section 971 of this title shall be subject to the following penalties:

(1) Except as provided in paragraph (2), any such person shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. Sections 842(c)(1) and (c)(3) of this title shall apply to any civil penalty assessed under this paragraph.

(2) If such a violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, such person shall be sentenced to imprisonment for not more than one year or a fine of not more than $25,000 or both.

(Pub. L. 91–513, title III, § 1011, Oct. 27, 1970, 84 Stat. 1290; Pub. L. 100–690, title VI, § 6053(d), Nov. 18, 1988, 102 Stat. 4316.)

AMENDMENTS

1988—Pub. L. 100–690 inserted ''or fails to notify the Attorney General of an importation or exportation under section 971 of this title''.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100–690, set out as a note under section 802 of this title.

## § 962. Second or subsequent offenses

### (a) Term of imprisonment and fine

Any person convicted of any offense under this subchapter is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both. If the conviction is for an offense punishable under section 960(b) of this title, and if it is the offender's second or subsequent offense, the court shall impose, in addition to any term of imprisonment and fine, twice the term of supervised release otherwise authorized.

### (b) Determination of status

For purposes of this section, a person shall be considered convicted of a second or subsequent offense if, prior to the commission of such offense, one or more prior convictions of such person for a felony drug offense have become final.

### (c) Procedures applicable

Section 851 of this title shall apply with respect to any proceeding to sentence a person under this section.

(Pub. L. 91–513, title III, § 1012, Oct. 27, 1970, 84 Stat. 1290; Pub. L. 98–473, title II, §§ 225(b), 505, Oct. 12, 1984, 98 Stat. 2030, 2070; Pub. L. 99–570, title I, §§ 1004(a), 1005(c), Oct. 27, 1986, 100 Stat. 3207–6; Pub. L. 103–322, title IX, § 90105(b), Sept. 13, 1994, 108 Stat. 1988.)

AMENDMENTS

1994—Subsec. (b). Pub. L. 103–322 substituted ''one or more prior convictions of such person for a felony drug offense have become final'' for ''one or more prior convictions of him for a felony under any provision of this subchapter or subchapter I of this chapter or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant drugs, have become final''.

1986—Subsec. (a). Pub. L. 99–570, § 1005(c), amended Pub. L. 98–473, § 225. See 1984 Amendment note below.

Pub. L. 99–570, § 1004(a), substituted ''term of supervised release'' for ''special parole term''.

1984—Subsec. (a). Pub. L. 98–473, § 225(b), which directed amendment of this section effective Nov. 1, 1987 (see section 235(a)(1) of Pub. L. 98–473 set out as an Effective Date note under section 3551 of Title 18, Crimes and Criminal Procedure) was omitted in the general amendment of section 225 of Pub. L. 98–473 by Pub. L. 99–570, § 1005(c).

Subsec. (b). Pub. L. 98–473, § 505, inserted references to laws of a State or of a foreign country.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 1004(a) of Pub. L. 99–570 effective on date of taking effect of section 3583 of Title 18, Crimes and Criminal Procedure (Nov. 1, 1987), see section 1004(b) of Pub. L. 99–570 set out as a note under section 841 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 46 App. section 1903.

## § 963. Attempt and conspiracy

Any person who attempts or conspires to commit any offense defined in this subchapter shall

be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

(Pub. L. 91–513, title III, § 1013, Oct. 27, 1970, 84 Stat. 1291; Pub. L. 100–690, title VI, § 6470(a), Nov. 18, 1988, 102 Stat. 4377.)

AMENDMENTS

1988—Pub. L. 100–690 substituted ''shall be subject to the same penalties as those prescribed for the offense'' for ''is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 18 sections 36, 3553.

### § 964. Additional penalties

Any penalty imposed for violation of this subchapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

(Pub. L. 91–513, title III, § 1014, Oct. 27, 1970, 84 Stat. 1291.)

### § 965. Applicability of part E of subchapter I

Part E of subchapter I of this chapter shall apply with respect to functions of the Attorney General (and of officers and employees of the Bureau of Narcotics and Dangerous Drugs) under this subchapter, to administrative and judicial proceedings under this subchapter, and to violations of this subchapter, to the same extent that such part applies to functions of the Attorney General (and such officers and employees) under subchapter I of this chapter, to such proceedings under subchapter I of this chapter, and to violations of subchapter I of this chapter. For purposes of the application of this section to section 880 or 881 of this title, any reference in such section 880 or 881 of this title to ''this subchapter'' shall be deemed to be a reference to this subchapter, any reference to section 823 of this title shall be deemed to be a reference to section 958 of this title, and any reference to section 822(d) of this title shall be deemed to be a reference to section 957(b)(2) of this title.

(Pub. L. 91–513, title III, § 1015, Oct. 27, 1970, 84 Stat. 1291; Pub. L. 95–633, title III, § 301(b), Nov. 10, 1978, 92 Stat. 3778.)

AMENDMENTS

1978—Pub. L. 95–633 inserted ''or 881'' after ''880'' wherever appearing.

TRANSFER OF FUNCTIONS

For abolition of Bureau of Narcotics and Dangerous Drugs, including Office of Director thereof, and creation of a single comprehensive agency for enforcement of drug laws by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, see note set out under section 881 of this title.

### § 966. Authority of Secretary of the Treasury

Nothing in this chapter shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

(Pub. L. 91–513, title III, § 1016, Oct. 27, 1970, 84 Stat. 1291.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original ''this Act'', meaning Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236, as amended. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

The customs laws, referred to in text, are classified generally to Title 19, Customs Duties.

### § 967. Smuggling of controlled substances; investigations; oaths; subpenas; witnesses; evidence; production of records; territorial limits; fees and mileage of witnesses

For the purpose of any investigation which, in the opinion of the Secretary of the Treasury, is necessary and proper to the enforcement of section 545 of title 18 (relating to smuggling goods into the United States) with respect to any controlled substance (as defined in section 802 of this title), the Secretary of the Treasury may administer oaths and affirmations, subpena witnesses, compel their attendance, take evidence, and require the production of records (including books, papers, documents and tangible things which constitute or contain evidence) relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place within the customs territory of the United States, except that a witness shall not be required to appear at any hearing distant more than 100 miles from the place where he was served with subpena. Witnesses summoned by the Secretary shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. Oaths and affirmations may be made at any place subject to the jurisdiction of the United States.

(Aug. 11, 1955, ch. 800, § 1, 69 Stat. 684; Oct. 27, 1970, Pub. L. 91–513, title III, § 1102(t), 84 Stat. 1294.)

CODIFICATION

Section was not enacted as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970 which comprises this chapter.

Section was formerly classified to section 1034 of Title 31 prior to the general revision and enactment of Title 31, Money and Finance, by Pub. L. 97–258, § 1, Sept. 13, 1982, 96 Stat. 877.

Section was also formerly classified to section 198a of this title.

AMENDMENTS

1970—Pub. L. 91–513 substituted ''section 545 of title 18 (relating to smuggling goods into the United States) with respect to any controlled substance (as defined in section 802 of this title)'' for ''the laws of the United States relating to narcotic drugs and marihuana'' and substituted the customs territory of the United States for any State or any territory or other place subject to the jurisdiction of the United States is the defined area from within which the attendance of witnesses and the production of records may be required, and struck out provisions making the discretion of the Secretary of the Treasury the determinative factor as to what is relevant or material to the investigation.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see 1105(a) of Pub. L. 91–513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of amendment

of this section by section 1102 of Pub. L. 91–513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91–513, set out as a note under sections 171 to 174 of this title.

### § 968. Service of subpena; proof of service

A subpena of the Secretary of the Treasury may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered on a true copy thereof by the person serving it shall be proof of service.

(Aug. 11, 1955, ch. 800, § 2, 69 Stat. 685.)

CODIFICATION

Section was not enacted as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970 which comprises this chapter.

Section was formerly classified to section 1035 of Title 31 prior to the general revision and enactment of Title 31, Money and Finance, by Pub. L. 97–258, § 1, Sept. 13, 1982, 96 Stat. 877.

Section was also formerly classified to section 198b of this title.

### § 969. Contempt proceedings

In case of contumacy by, or refusal to obey a subpena issued to, any person, the Secretary of the Treasury may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, carries on business or may be found, to compel compliance with the subpena of the Secretary of the Treasury. The court may issue an order requiring the subpenaed person to appear before the Secretary of the Treasury there to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in the judicial district whereof the subpenaed person is an inhabitant or wherever he may be found.

(Aug. 11, 1955, ch. 800, § 3, 69 Stat. 685.)

CODIFICATION

Section was not enacted as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970 which comprises this chapter.

Section was formerly classified to section 1036 of Title 31 prior to the general revision and enactment of Title 31, Money and Finance, by Pub. L. 97–258, § 1, Sept. 13, 1982, 96 Stat. 877.

Section was also formerly classified to section 198c of this title.

### § 970. Criminal forfeitures

Section 853 of this title, relating to criminal forfeitures, shall apply in every respect to a violation of this subchapter punishable by imprisonment for more than one year.

(Pub. L. 91–513, title III, § 1017, as added Pub. L. 98–473, title II, § 307, Oct. 12, 1984, 98 Stat. 2051.)

### § 971. Notification, suspension of shipment, and penalties with respect to importation and exportation of listed chemicals

#### (a) Notification prior to transaction

Each regulated person who imports or exports a listed chemical shall notify the Attorney General of the importation or exportation not later than 15 days before the transaction is to take place.

#### (b) Regular customers or importers

(1) The Attorney General shall provide by regulation for circumstances in which the requirement of subsection (a) of this section does not apply to a transaction between a regulated person and a regular customer or to an importation by a regular importer. At the time of any importation or exportation constituting a transaction referred to in the preceding sentence, the regulated person shall notify the Attorney General of the transaction.

(2) The regulations under this subsection shall provide that the initial notification under subsection (a) of this section with respect to a customer of a regulated person or to an importer shall, upon the expiration of the 15-day period, qualify the customer as a regular customer or the importer as a regular importer, unless the Attorney General otherwise notifies the regulated person in writing.

#### (c) Suspension of importation or exportation; disqualification of regular customers or importers; hearing

(1) The Attorney General may order the suspension of any importation or exportation of a listed chemical (other than a regulated transaction to which the requirement of subsection (a) of this section does not apply by reason of subsection (b) of this section) or may disqualify any regular customer or regular importer on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance. From and after the time when the Attorney General provides written notice of the order (including a statement of the legal and factual basis for the order) to the regulated person, the regulated person may not carry out the transaction.

(2) Upon written request to the Attorney General, a regulated person to whom an order applies under paragraph (1) is entitled to an agency hearing on the record in accordance with subchapter II of chapter 5 of title 5. The hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time, if so requested by the regulated person.

#### (d) Broker or trader for international transaction in listed chemical

A person located in the United States who is a broker or trader for an international transaction in a listed chemical that is a regulated transaction solely because of that person's involvement as a broker or trader shall, with respect to that transaction, be subject to all of the notification, reporting, recordkeeping, and other requirements placed upon exporters of listed chemicals by this subchapter and subchapter I of this chapter.

**(e) Application of notification requirement to exports of listed chemical; waiver**

(1) The Attorney General may by regulation require that the 15-day notification requirement of subsection (a) of this section apply to all exports of a listed chemical to a specified country, regardless of the status of certain customers in such country as regular customers, if the Attorney General finds that such notification is necessary to support effective chemical diversion control programs or is required by treaty or other international agreement to which the United States is a party.

(2) The Attorney General may by regulation waive the 15-day notification requirement for exports of a listed chemical to a specified country if the Attorney General determines that such notification is not required for effective chemical diversion control. If the notification requirement is waived, exporters of the listed chemical shall be required to submit to the Attorney General reports of individual exportations or periodic reports of such exportation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

(3) The Attorney General may by regulation waive the 15-day notification requirement for the importation of a listed chemical if the Attorney General determines that such notification is not necessary for effective chemical diversion control. If the notification requirement is waived, importers of the listed chemical shall be required to submit to the Attorney General reports of individual importations or periodic reports of the importation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

(Pub. L. 91–513, title III, § 1018, as added Pub. L. 100–690, title VI, § 6053(a), Nov. 18, 1988, 102 Stat. 4314; amended Pub. L. 103–200, §§ 4(a), 5(a), 9(b), Dec. 17, 1993, 107 Stat. 2338–2340; Pub. L. 103–322, title XXXIII, § 330024(c), Sept. 13, 1994, 108 Stat. 2150.)

AMENDMENTS

1994—Subsecs. (b)(1), (2), (c)(1). Pub. L. 103–322, § 330024(c)(2), made technical amendment to directory language of Pub. L. 103–200, § 9(b). See 1993 Amendment notes below.

Subsec. (e). Pub. L. 103–322, § 330024(c)(1), made technical amendment to directory language of Pub. L. 103–200, § 5(a). See 1993 Amendment note below.

1993—Subsec. (b)(1). Pub. L. 103–200, § 9(b)(1)(A), as amended by Pub. L. 103–322, § 330024(c)(2), substituted ''to an importation by a regular importer'' for ''regular supplier of the regulated person''.

Subsec. (b)(2). Pub. L. 103–200, § 9(b)(1)(B), as amended by Pub. L. 103–322, § 330024(c)(2), substituted ''a customer of a regulated person or to an importer'' for ''a customer or supplier of a regulated person'' and ''the importer as a regular importer'' for ''regular supplier''.

Subsec. (c)(1). Pub. L. 103–200, § 9(b)(2), as amended by Pub. L. 103–322, § 330024(c)(2), substituted ''regular importer'' for ''regular supplier''.

Subsec. (d). Pub. L. 103–200, § 4(a), added subsec. (d).

Subsec. (e). Pub. L. 103–200, § 5(a), as amended by Pub. L. 103–322, § 330024(c)(1), added subsec. (e).

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub. L. 103–322, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE

Section 6053(b) of Pub. L. 100–690 provided that:

''(1) Not later than 45 days after the date of the enactment of this Act [Nov. 18, 1988], the Attorney General shall forward to the Director of the Office of Management and Budget proposed regulations required by the amendment made by subsection (a) [enacting this section].

''(2) Not later than 55 days after the date of the enactment of this Act, the Director of the Office of Management and Budget shall—

''(A) review such proposed regulations of the Attorney General; and

''(B) forward any comments and recommendations for modifications to the Attorney General.

''(3) Not later than 60 days after the date of the enactment of this Act, the Attorney General shall publish the proposed final regulations required by the amendment made by subsection (a).

''(4) Not later than 120 days after the date of the enactment of this Act, the Attorney General shall promulgate final regulations required by the amendment made by subsection (a).

''(5) Subsection (a) of section 1018 of the Controlled Substances Import and Export Act [subsection (a) of this section], as added by subsection (a) of this section, shall take effect 90 days after the promulgation of the final regulations under paragraph (4).

''(6) Each regulated person shall provide to the Attorney General the identity of any regular customer or regular supplier of the regulated person not later than 30 days after the promulgation of the final regulations under paragraph (4). Not later than 60 days after the end of such 30-day period, each regular customer and regular supplier so identified shall be a regular customer or regular supplier for purposes of any applicable exception from the requirement of subsection (a) of such section 1018, unless the the [sic] Attorney General otherwise notifies the regulated person in writing.''

Section effective 120 days after Nov. 18, 1988 [except subsec. (a), see above], see section 6061 of Pub. L. 100–690, set out as an Effective Date of 1988 Amendment note under section 802 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 960, 961 of this title.

## CHAPTER 14—ALCOHOL AND DRUG ABUSE EDUCATIONAL PROGRAMS AND ACTIVITIES

### §§ 1001 to 1007. Repealed. Pub. L. 97–35, title V, § 587(a)(3), Aug. 13, 1981, 95 Stat. 480

Section 1001, Pub. L. 91–527, § 2, Dec. 3, 1970, 84 Stat. 1385; Pub. L. 93–422, § 2(b), Sept. 21, 1974, 88 Stat. 1154; Pub. L. 95–336, § 2, Aug. 4, 1978, 92 Stat. 451, set forth Congressional declaration of purpose for Alcohol and Drug Abuse Education Act.

Section 1002, Pub. L. 91–527, § 3, Dec. 3, 1970, 84 Stat. 1386; Pub. L. 93–422, § 2(c), Sept. 21, 1974, 88 Stat. 1155; Pub. L. 95–336, §§ 3, 4, Aug. 4, 1978, 92 Stat. 451, 452; S. Res. 30, Mar. 7, 1979; Pub. L. 96–88, title III, § 301(a)(1), (2)(Q), (b)(1), title V, § 507, Oct. 17, 1979, 93 Stat. 677, 678, 692, set forth grant and contract authority, etc., for projects and programs.

Section 1003, Pub. L. 91–527, § 4, Dec. 3, 1970, 84 Stat. 1387; Pub. L. 93–422, § 2(d), Sept. 21, 1974, 88 Stat. 1157; Pub. L. 96–88, title III, § 301(a)(1), title V, § 507, Oct. 17, 1979, 93 Stat. 677, 692, related to recordkeeping requirements, and access to and inspection of records.

Section 1004, Pub. L. 91–527, § 5, Dec. 3, 1970, 84 Stat. 1388; Pub. L. 93–422, § 2(e), Sept. 21, 1974, 88 Stat. 1157; Pub. L. 96–88, title V, § 508(i), Oct. 17, 1979, 93 Stat. 693, related to technical assistance to local agencies, etc.

Section 1005, Pub. L. 91–527, § 6, Dec. 3, 1970, 84 Stat. 1388, related to nature of payments.

Section 1006, Pub. L. 91–527, § 7, Dec. 3, 1970, 84 Stat. 1388, related to utilization of services and facilities of Federal agencies and public and private agencies and institutions.

Section 1007, Pub. L. 91–527, § 8, Dec. 3, 1970, 84 Stat. 1388; Pub. L. 93–422, § 2(f), Sept. 21, 1974, 88 Stat. 1157; Pub. L. 95–336, § 5, Aug. 4, 1978, 92 Stat. 453; Pub. L. 96–88, title III, § 301(a)(1), (2)(Q), title V, § 507, Oct. 17, 1979, 93 Stat. 677, 678, 692, defined ''Secretary'' and ''State''.

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1982, see section 587(a) of Pub. L. 97–35, set out as section 3863(a) of Title 20, Education.

## CHAPTER 15—EGG PRODUCTS INSPECTION

Sec.
1031. Congressional statement of findings.
1032. Congressional declaration of policy.
1033. Definitions.
1034. Inspection of egg products.
(a) Processing operations and establishments subject to coverage; rules and regulations.
(b) Authority of Secretary to retain, segregate, and reinspect eggs and egg products.
(c) Condemnation of adulterated products; destruction or reprocessing; procedure upon appeal from determination of adulteration.
(d) Inspection of business premises, facilities, inventory, operations, and records of egg handlers; inspection of records and inventory of others required to keep records; authority of Secretary of Health and Human Services to inspect food manufacturing establishments, institutions, and restaurants; access to places of business.
1035. Sanitary operating practices in official plants.
(a) Premises, facilities, and equipment.
(b) Refusal by Secretary to inspect nonconforming plants.
1036. Pasteurization and labeling of egg products at official plants.
(a) Contents of label.
(b) False or misleading or use of nonapproved labeling or containers; determination by Secretary; procedures applicable; appeal.
1037. Prohibited acts.
1038. Cooperation with appropriate State and other governmental agencies; utilization of employees; reimbursement.
1039. Eggs and egg products not intended for use as human food; inspection; denaturing or otherwise identifying.
1040. Recordkeeping requirements; persons required to maintain records; scope of disclosure; access to records.
1041. Enforcement provisions.
(a) Violations of section 1037; term of imprisonment and fine; scope of liability.
(b) Penalties applicable to carriers or warehousemen.
(c) Persons preventing enforcement of chapter; term of imprisonment and fine.
1042. Reporting of violation to United States attorney for institution of criminal proceedings; procedure; presentation of views.
1043. Rules and regulations; administration and enforcement.
Sec.
1044. Exemption of certain activities.
(a) Regulation for exemptions.
(b) Plants located in noncontiguous areas of United States.
(c) Suspension or termination of exemptions.
1045. Limitation on entry of eggs and egg products and other materials into official plants.
1046. Imports.
(a) Authorization for importation of restricted eggs; prerequisites for importation of egg products; treatment as domestic articles subject to this chapter; marking and labeling exemption for personal consumption.
(b) Terms and conditions for destruction.
(c) Payment of storage, cartage, and labor charges by owner or consignee; liens.
(d) Prohibition.
1047. Refusal or withdrawal of inspection services; hearing; grounds; person deemed to have responsible connection with business; finality of order of Secretary; judicial review; other provisions for refusal of services unaffected.
1048. Administrative detention of violative articles; duration; release; removal of official marks.
1049. Seizure and condemnation proceedings.
(a) Jurisdiction; disposal of condemned articles; court costs and fees; conformity to supplemental rules for admiralty and maritime claims; jury trial; United States as plaintiff.
(b) Condemnation or seizure under other provisions unaffected.
1050. Jurisdiction of district courts; United States as plaintiff in enforcement and restraining proceedings; subpenas for witnesses.
1051. Other Federal laws applicable for administration and enforcement of chapter; prosecution of inquiries; exercise of jurisdiction.
1052. State or local regulation.
(a) Prohibition against additional or different requirements than Federal requirements relating to premises, facilities, and operations at official plants; authority to impose recordkeeping and related requirements consistent with Federal requirements.
(b) Prohibition against additional or different standards than Federal standards of quality, etc., or requiring labeling to show area of production or origin; authority to require name, address, and license number of processor or packer on containers; prohibition against additional or different requirements than Federal requirements relating to labeling, packaging or ingredients; authority to prevent distribution of violative articles; validity of nonconflicting laws.
(c) Applicability of other Federal laws and authority of other Federal officials relating to eggs, egg products, or other food products unaffected; authority of Secretary of Agriculture to regulate official plants processing egg products.
(d) Detainer authority.
1053. Inspection and administration costs.
(a) Overtime and holiday work costs; availability of funds.
(b) ''Holiday'' defined.

Sec.
1054. Annual report to Congressional committees.
1055. Authorization of appropriations.
1056. Separability.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in title 7 section 6519.

## § 1031. Congressional statement of findings

Eggs and egg products are an important source of the Nation's total supply of food, and are used in food in various forms. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed herein for assuring that eggs and egg products distributed to them and used in products consumed by them are wholesome, otherwise not adulterated, and properly labeled and packaged. Lack of effective regulation for the handling or disposition of unwholesome, otherwise adulterated, or improperly labeled or packaged egg products and certain qualities of eggs is injurious to the public welfare and destroys markets for wholesome, not adulterated, and properly labeled and packaged eggs and egg products and results in sundry losses to producers and processors, as well as injury to consumers. Unwholesome, otherwise adulterated, or improperly labeled or packaged products can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged products, to the detriment of consumers and the public generally. It is hereby found that all egg products and the qualities of eggs which are regulated under this chapter are either in interstate or foreign commerce, or substantially affect such commerce, and that regulation by the Secretary of Agriculture and the Secretary of Health and Human Services, and cooperation by the States and other jurisdictions, as contemplated by this chapter, are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

(Pub. L. 91–597, § 2, Dec. 29, 1970, 84 Stat. 1620; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original ''this Act'', meaning Pub. L. 91–597, Dec. 29, 1970, 84 Stat. 1620, as amended, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under this section. For complete classification of this Act to the Code, see Short Title note set out below and Tables.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in text pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE

Section 29 of Pub. L. 91–597 provided that: ''The provisions of this Act [enacting this chapter, amending sections 633 and 636 of Title 15, Commerce and Trade, and enacting provisions set out as notes under this section] with respect to egg products shall take effect six months after enactment [Dec. 29, 1970]. Otherwise, this Act shall take effect eighteen months after enactment.''

SHORT TITLE

Section 1 of Pub. L. 91–597 provided: ''That this Act [enacting this chapter, amending sections 633 and 636 of Title 15, Commerce and Trade, and enacting provisions set as notes under this section] may be cited as the 'Egg Products Inspection Act'.''

MAINTENANCE OF EGGS AT PROPER TEMPERATURE

Pub. L. 102–237, title X, § 1012(a), Dec. 13, 1991, 105 Stat. 1899, provided that:

''(1) FINDINGS.—Congress finds that—

''(A) food borne illness is a serious health problem;

''(B) its incidence can be reduced through proper handling of food; and

''(C) eggs are perishable and therefore are particularly susceptible to supporting microbial growth if proper temperature controls are not maintained.

''(2) PURPOSES.—It is the purpose of this section [amending sections 1034, 1037, 1041, 1042, 1046, and 1052 of this title and enacting provisions set out as a note under section 1034 of this title] to prescribe the temperature at which eggs are maintained in order to reduce the potential for harmful microbial growth to protect the health and welfare of consumers.''

## § 1032. Congressional declaration of policy

It is hereby declared to be the policy of the Congress to provide for the inspection of certain egg products, restrictions upon the disposition of certain qualities of eggs, and uniformity of standards for eggs, and otherwise regulate the processing and distribution of eggs and egg products as hereinafter prescribed to prevent the movement or sale for human food, of eggs and egg products which are adulterated or misbranded or otherwise in violation of this chapter.

(Pub. L. 91–597, § 3, Dec. 29, 1970, 84 Stat. 1621.)

## § 1033. Definitions

For purposes of this chapter—

(a) The term ''adulterated'' applies to any egg or egg product under one or more of the following circumstances—

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;

(D) if it bears or contains any color additive which is unsafe within the meaning of section

379e of this title: *Provided*, That an article which is not otherwise deemed adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive, in or on such article, is prohibited by regulations of the Secretary in official plants;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human food;

(4) if it has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is an egg which has been subjected to incubation or the product of any egg which has been subjected to incubation;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title; or

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(b) The term ''capable of use as human food'' shall apply to any egg or egg product, unless it is denatured, or otherwise identified, as required by regulations prescribed by the Secretary to deter its use as human food.

(c) The term ''commerce'' means interstate, foreign, or intrastate commerce.

(d) The term ''container'' or ''package'' includes any box, can, tin, plastic, or other receptacle, wrapper, or cover.

(1) The term ''immediate container'' means any consumer package; or any other container in which egg products, not consumer packaged, are packed.

(2) The term ''shipping container'' means any container used in packaging a product packed in an immediate container.

(e) The term ''egg handler'' means any person who engages in any business in commerce which involves buying or selling any eggs (as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food.

(f) The term ''egg product'' means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products.

(g) The term ''egg'' means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

(1) The term ''check'' means an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(2) The term ''clean and sound shell egg'' means any egg whose shell is free of adhering dirt or foreign material and is not cracked or broken.

(3) The term ''dirty egg'' means an egg that has a shell that is unbroken and has adhering dirt or foreign material.

(4) The term ''incubator reject'' means an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(5) The term ''inedible'' means eggs of the following descriptions: black rots, yellow rots, white rots, mixed rots (addled eggs), sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage.)

(6) The term ''leaker'' means an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(7) The term ''loss'' means an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

(8) The term ''restricted egg'' means any check, dirty egg, incubator reject, inedible, leaker, or loss.

(h) The term ''Fair Packaging and Labeling Act'' [15 U.S.C. 1451 et seq.] means the Act so entitled, approved November 3, 1966, (80 Stat. 1296), and Acts amendatory thereof or supplementary thereto.

(i) The term ''Federal Food, Drug, and Cosmetic Act'' [21 U.S.C. 301 et seq.] means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

(j) The term ''inspection'' means the application of such inspection methods and techniques as are deemed necessary by the responsible Secretary to carry out the provisions of this chapter.

(k) The term ''inspector'' means:

(1) any employee or official of the United States Government authorized to inspect eggs or egg products under the authority of this chapter; or

(2) any employee or official of the government of any State or local jurisdiction authorized by the Secretary to inspect eggs or egg products under the authority of this chapter, under an agreement entered into between the Secretary and the appropriate State or other agency.

(*l*) The term ''misbranded'' shall apply to egg products which are not labeled and packaged in accordance with the requirements prescribed by

regulations of the Secretary under section 1036 of this title.

(m) The term ''official certificate'' means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(n) The term ''official device'' means any device prescribed or authorized by the Secretary for use in applying any official mark.

(*o*) The term ''official inspection legend'' means any symbol prescribed by regulations of the Secretary showing that egg products were inspected in accordance with this chapter.

(p) The term ''official mark'' means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article under this chapter.

(q) The term ''official plant'' means any plant, as determined by the Secretary, at which inspection of the processing of egg products is maintained by the Department of Agriculture under the authority of this chapter.

(r) The term ''official standards'' means the standards of quality, grades, and weight classes for eggs, in effect upon the effective date of this chapter, or as thereafter amended, under the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; 7 U.S.C. 1621 et seq.).

(s) The term ''pasteurize'' means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable micro-organisms by such processes as may be prescribed by regulations of the Secretary.

(t) The term ''person'' means any individual, partnership, corporation, association, or other business unit.

(u) The terms ''pesticide chemical,'' ''food additive,'' ''color additive,'' and ''raw agricultural commodity'' shall have the same meaning for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(v) The term ''plant'' means any place of business where egg products are processed.

(w) The term ''processing'' means manufacturing egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products.

(x) The term ''Secretary'' means the Secretary of Agriculture or his delegate.

(y) The term ''State'' means any State of the United States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and the District of Columbia.

(z) The term ''United States'' means the States.

(Pub. L. 91–597, § 4, Dec. 29, 1970, 84 Stat. 1621; Pub. L. 102–571, title I, § 107(15), Oct. 29, 1992, 106 Stat. 4499.)

REFERENCES IN TEXT

The Fair Packaging and Labeling Act, referred to in subsec. (h), is Pub. L. 89–755, Nov. 3, 1966, 80 Stat. 1296, as amended, which is classified generally to chapter 39 (§ 1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1451 of Title 15 and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (i) and (u), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

The effective date of this chapter, referred to in subsec. (r), means the effective date of Pub. L. 91–597. For such effective date, see Effective Date note set out under section 1031 of this title.

The Agricultural Marketing Act of 1946, referred to in subsec. (r), is title II of act Aug. 14, 1946, ch. 966, 60 Stat. 1087, as amended, which is classified generally to chapter 38 (§ 1621 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 1621 of Title 7 and Tables.

AMENDMENTS

1992—Subsec. (a)(2)(D). Pub. L. 102–571 substituted ''379e'' for ''376''.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1041 of this title; title 15 sections 2052, 2602.

## § 1034. Inspection of egg products

### (a) Processing operations and establishments subject to coverage; rules and regulations

For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any egg product which is capable of use as human food and is misbranded or adulterated, the Secretary shall, whenever processing operations are being conducted, cause continuous inspection to be made, in accordance with the regulations promulgated under this chapter, of the processing of egg products, in each plant processing egg products for commerce, unless exempted under section 1044 of this title. Without restricting the application of the preceding sentence to other kinds of establishments within its provisions, any food manufacturing establishment, institution, or restaurant which uses any eggs that do not meet the requirements of section 1044(a)(1) of this title in the preparation of any articles for human food shall be deemed to be a plant processing egg products, with respect to such operations.

### (b) Authority of Secretary to retain, segregate, and reinspect eggs and egg products

The Secretary, at any time, shall cause such retention, segregation, and reinspection as he deems necessary of eggs and egg products capable of use as human food in each official plant.

### (c) Condemnation of adulterated products; destruction or reprocessing; procedure upon appeal from determination of adulteration

Eggs and egg products found to be adulterated at official plants shall be condemned and, if no appeal be taken from such determination of condemnation, such articles shall be destroyed for human food purposes under the supervision of an inspector: *Provided*, That articles which may by reprocessing be made not adulterated need not be condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated. If an appeal be taken from such determination, the eggs or egg products shall be appropriately marked and segregated pending completion of an appeal inspection, which appeal shall be at the cost of the ap-

pellant if the Secretary determines that the appeal is frivolous. If the determination of condemnation is sustained, the eggs or egg products shall be destroyed for human food purposes under the supervision of an inspector.

**(d) Inspection of business premises, facilities, inventory, operations, and records of egg handlers; inspection of records and inventory of others required to keep records; authority of Secretary of Health and Human Services to inspect food manufacturing establishments, institutions, and restaurants; access to places of business**

The Secretary shall cause such other inspections to be made of the business premises, facilities, inventory, operations, and records of egg handlers, and the records and inventory of other persons required to keep records under section 1040 of this title, as he deems appropriate (and in the case of shell egg packers, packing eggs for the ultimate consumer, at least once each calendar quarter) to assure that only eggs fit for human food are used for such purpose, and otherwise to assure compliance by egg handlers and other persons with the requirements of section 1037 of this title, except that the Secretary of Health and Human Services shall cause such inspections to be made as he deems appropriate to assure compliance with such requirements at food manufacturing establishments, institutions, and restaurants, other than plants processing egg products. Representatives of said Secretaries shall be afforded access to all such places of business for purposes of making the inspections provided for in this chapter.

(Pub. L. 91–597, § 5, Dec. 29, 1970, 84 Stat. 1624; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–237, title X, § 1012(b), Dec. 13, 1991, 105 Stat. 1899.)

ENACTMENT OF SUBSECTION (e)

*Pub. L. 102–237, title X, § 1012(b), (h), Dec. 13, 1991, 105 Stat. 1899, 1901, provided that, effective 12 months after promulgation of final implementing regulations, this section is amended by adding the following new subsection:*

*(e) Refrigeration and labeling requirements*

*(1) Subject to paragraphs (2), (3), and (4), the Secretary shall make such inspections as the Secretary considers appropriate of a facility of an egg handler (including a transport vehicle) to determine if shell eggs destined for the ultimate consumer—*

*(A) are being held under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit after packing; and*

*(B) contain labeling that indicates that refrigeration is required.*

*(2) In the case of a shell egg packer packing eggs for the ultimate consumer, the Secretary shall make an inspection in accordance with paragraph (1) at least once each calendar quarter.*

*(3) The Secretary of Health and Human Services shall cause such inspections to be made as the Secretary considers appropriate to ensure compliance with the requirements of paragraph (1) at food manufacturing establishments, institutions, and restaurants, other than plants packing eggs.*

*(4) The Secretary shall not make an inspection as provided in paragraph (1) on any egg handler with a flock of not more than 3,000 layers.*

*(5) A representative of the Secretary and the Secretary of Health and Human Services shall be afforded access to a place of business referred to in this subsection, including a transport vehicle, for purposes of making an inspection required under this subsection.*

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (d) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1991 AMENDMENT

Section 1012(h) of Pub. L. 102–237 provided that: "This section and the amendments made by this section [amending this section and sections 1037, 1041, 1042, 1046, and 1052 of this title and enacting provisions set out as a note under section 1031 of this title] shall become effective 12 months after the Secretary of Agriculture promulgates final regulations implementing this section and the amendments."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1043, 1046, 1052 of this title.

## § 1035. Sanitary operating practices in official plants

**(a) Premises, facilities, and equipment**

Each official plant shall be operated in accordance with such sanitary practices and shall have such premises, facilities, and equipment as are required by regulations promulgated by the Secretary to effectuate the purposes of this chapter, including requirements for segregation and disposition of restricted eggs.

**(b) Refusal by Secretary to inspect nonconforming plants**

The Secretary shall refuse to render inspection to any plant whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section.

(Pub. L. 91–597, § 6, Dec. 29, 1970, 84 Stat. 1625.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1037 of this title.

## § 1036. Pasteurization and labeling of egg products at official plants

**(a) Contents of label**

Egg products inspected at any official plant under the authority of this chapter and found to be not adulterated shall be pasteurized before they leave the official plant, except as otherwise permitted by regulations of the Secretary, and shall at the time they leave the official plant, bear in distinctly legible form on their shipping containers or immediate containers, or both, when required by regulations of the Secretary, the official inspection legend and official plant number, of the plant where the products were processed, and such other information as the Secretary may require by regulations to describe the products adequately and to assure that they will not have false or misleading labeling.

**(b) False or misleading or use of nonapproved labeling or containers; determination by Secretary; procedures applicable; appeal**

No labeling or container shall be used for egg products at official plants if it is false or misleading or has not been approved as required by the regulations of the Secretary. If the Secretary has reason to believe that any labeling or the size or form of any container in use or proposed for use with respect to egg products at any official plant is false or misleading in any particular, he may direct that such use be withheld unless the labeling or container is modified in such manner as he may prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Secretary, such person may request a hearing, but the use of the labeling or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person adversely affected thereby appeals to the United States court of appeals for the circuit in which such person has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 194 of title 7, shall be applicable to appeals taken under this section.

(Pub. L. 91–597, § 7, Dec. 29, 1970, 84 Stat. 1625.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1033, 1037 of this title.

**§ 1037. Prohibited acts**

(a)(1) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in any business in commerce any restricted eggs, capable of use as human food, except as authorized by regulations of the Secretary under such conditions as he may prescribe to assure that only eggs fit for human food are used for such purpose.

(2) No egg handler shall possess with intent to use, or use, any restricted eggs in the preparation of human food for commerce except that such eggs may be so possessed and used when authorized by regulations of the Secretary under such conditions as he may prescribe to assure that only eggs fit for human food are used for such purpose.

(b)(1) No person shall process any egg products for commerce at any plant except in compliance with the requirements of this chapter.

(2) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in commerce any egg products required to be inspected under this chapter unless they have been so inspected and are labeled and packaged in accordance with the requirements of section 1036 of this title.

(3) No operator of any official plant shall fail to comply with any requirements of section 1035(a) of this title or the regulations thereunder.

(4) No operator of any official plant shall allow any egg products to be moved from such plant if they are adulterated or misbranded and capable of use as human food.

(c) No person shall violate any provision of section 1039, 1040 or 1046 of this title.

(d) No person shall—

(1) manufacture, cast, print, lithograph, or otherwise make any device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, or any form of official certificate or simulation thereof, except as authorized by the Secretary;

(2) forge or alter any official device, mark, or certificate;

(3) without authorization from the Secretary, use any official device, mark, or certificate, or simulation thereof, or detach, deface, or destroy any official device or mark; or use any labeling or container ordered to be withheld from use under section 1036 of this title after final judicial affirmance of such order or expiration of the time for appeal if no appeal is taken under said section;

(4) contrary to the regulations prescribed by the Secretary, fail to use, or to detach, deface, or destroy any official device, mark, or certificate;

(5) knowingly possess, without promptly notifying the Secretary or his representative, any official device or any counterfeit, simulated, forged, or improperly altered official certificate or any device or label, or any eggs or egg products bearing any counterfeit, simulated, forged, or improperly altered official mark;

(6) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary;

(7) knowingly represent that any article has been inspected or exempted, under this chapter, when, in fact, it has, respectively, not been so inspected or exempted; and

(8) refuse access, at any reasonable time, to any representative of the Secretary of Agriculture or the Secretary of Health and Human Services, to any plant or other place of business subject to inspection under any provisions of this chapter.

(e) No person, while an official or employee of the United States Government or any State or local governmental agency, or thereafter, shall use to his own advantage, or reveal other than to the authorized representatives of the United States Government or any State or other government in their official capacity, or as ordered by a court in a judicial proceeding, any information acquired under the authority of this chapter concerning any matter which is entitled to protection as a trade secret.

(Pub. L. 91–597, § 8, Dec. 29, 1970, 84 Stat. 1626; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–237, title X, § 1012(c), Dec. 13, 1991, 105 Stat. 1899.)

AMENDMENT OF SECTION

*Pub. L. 102–237, title X, § 1012(c), (h), Dec. 13, 1991, 105 Stat. 1899, 1901, provided that, effective 12 months after promulgation of final implementing regulations, this section is amended by redesignating subsections (c) through (e) of*

*this section as (d) through (f), respectively, and by inserting after subsection (b) of this section the following new subsection:*

*(c) No egg handler shall possess any eggs after the eggs have been packed into a container that is destined for the ultimate consumer unless the eggs are stored and transported under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit, as prescribed by rules and regulations promulgated by the Secretary.*

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsec. (d)(8) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–237 effective 12 months after promulgation of final implementing regulations, see section 1012(h) of Pub. L. 102–237, set out as a note under section 1034 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1034, 1041, 1046 of this title.

### § 1038. Cooperation with appropriate State and other governmental agencies; utilization of employees; reimbursement

The Secretary shall, whenever he determines that it would effectuate the purposes of this chapter, cooperate with appropriate State and other governmental agencies, in carrying out any provisions of this chapter. In carrying out the provisions of this chapter, the Secretary may conduct such examinations, investigations, and inspections as he determines practicable through any officer or employee of any such agency commissioned by him for such purpose. The Secretary shall reimburse the States and other agencies for the costs incurred by them in such cooperative programs.

(Pub. L. 91–597, § 9, Dec. 29, 1970, 84 Stat. 1627.)

### § 1039. Eggs and egg products not intended for use as human food; inspection; denaturing or otherwise identifying

Inspection shall not be provided under this chapter at any plant for the processing of any egg products which are not intended for use as human food, but such articles, prior to their offer for sale or transportation in commerce, shall be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food. No person shall buy, sell, or transport or offer to buy or sell, or offer or receive for transportation, in commerce, any restricted eggs or egg products which are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary.

(Pub. L. 91–597, § 10, Dec. 29, 1970, 84 Stat. 1627.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1037 of this title.

### § 1040. Recordkeeping requirements; persons required to maintain records; scope of disclosure; access to records

For the purpose of enforcing the provisions of this chapter and the regulations promulgated thereunder, all persons engaged in the business of transporting, shipping, or receiving any eggs or egg products in commerce or holding such articles so received, and all egg handlers, shall maintain such records showing, for such time and in such form and manner, as the Secretary of Agriculture or the Secretary of Health and Human Services may prescribe, to the extent that they are concerned therewith, the receipt, delivery, sale, movement, and disposition of all eggs and egg products handled by them, and shall, upon the request of a duly authorized representative of either of said Secretaries, permit him at reasonable times to have access to and to copy all such records.

(Pub. L. 91–597, § 11, Dec. 29, 1970, 84 Stat. 1627; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.)

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1034, 1037, 1041, 1052 of this title.

### § 1041. Enforcement provisions

#### (a) Violations of section 1037; term of imprisonment and fine; scope of liability

Any person who commits any offense prohibited by section 1037 of this title shall upon conviction be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine, but if such violation involves intent to defraud, or any distribution or attempted distribution of any article that is known to be adulterated (except as defined in section 1033(a)(8) of this title), such person shall be subject to imprisonment for not more than three years or a fine of not more than $10,000, or both. When construing or enforcing the provisions of section 1037 of this title, the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association within the scope of his employment or office shall in every case be deemed the act, omission, or failure of such individual, partnership, corporation, or association, as well as of such person.

#### (b) Penalties applicable to carriers or warehousemen

No carrier or warehouseman shall be subject to the penalties of this chapter, other than the penalties for violation of section 1040 of this title or subsection (c) of this section, by reason of his receipt, carriage, holding, or delivery, in the usual course of business, as a carrier or warehouseman of eggs or egg products owned by another person unless the carrier or warehouseman has knowledge, or is in possession of facts

which would cause a reasonable person to believe that such eggs or egg products were not eligible for transportation under, or were otherwise in violation of, this chapter, or unless the carrier or warehouseman refuses to furnish on request of a representative of the Secretary the name and address of the person from whom he received such eggs or egg products and copies of all documents, if there be any, pertaining to the delivery of the eggs or egg products to, or by, such carrier or warehouseman.

**(c) Persons preventing enforcement of chapter; term of imprisonment and fine**

Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account of the performance of his official duties under this chapter shall be fined not more than $5,000 or imprisoned not more than three years or both. Whoever, in the commission of any such act, uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than ten years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this chapter shall be punished as provided under sections 1111 and 1112 of title 18.

(Pub. L. 91–597, § 12, Dec. 29, 1970, 84 Stat. 1628; Pub. L. 102–237, title X, § 1012(d), Dec. 13, 1991, 105 Stat. 1899.)

AMENDMENT OF SECTION

*Pub. L. 102–237, title X, § 1012(d), (h), Dec. 13, 1991, 105 Stat. 1899, 1901, provided that, effective 12 months after promulgation of final implementing regulations, this section is amended:*

*(1) in the first sentence of subsection (a) of this section, by striking ''$1,000'' and inserting ''$5,000'';*

*(2) by designating the last sentence of subsection (a) of this section as subsection (d) of this section and transferring such subsection to the end of this section;*

*(3) by redesignating subsection (b) of this section as (e) and transferring such subsection to the end of this section;*

*(4) by redesignating subsection (c) as (b); and*

*(5) by inserting after subsection (b) of this section the following new subsection:*

*(c) Civil penalty*

*(1)(A) Except as otherwise provided in this subsection, any person who violates any provision of this chapter or any regulation issued under this chapter, other than a violation for which a criminal penalty has been imposed under this chapter, may be assessed a civil penalty by the Secretary of not more than $5,000 for each such violation. Each violation to which this subparagraph applies shall be considered a separate offense.*

*(B) No penalty shall be assessed against any person under this subsection unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5.*

*(C) The amount of the civil penalty imposed under this subsection—*

*(i) shall be assessed by the Secretary, by written order, taking into account the gravity of the violation, degree of culpability, and history of prior offenses; and*

*(ii) may be reviewed only as provided in paragraph (2).*

*(2)(A) The determination and order of the Secretary under this subsection shall be final and conclusive unless the person against whom such a violation is found under paragraph (1) files an application for judicial review within 30 days after service of the order in the United States court of appeals for the circuit in which the person has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit.*

*(B) Judicial review of any such order shall be based on the record on which the determination and order are based.*

*(C) If the court determines that additional evidence needs to be taken, the court shall order the hearing to be reopened for this purpose in such manner and on such terms and conditions as the court considers proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, on the basis of the additional evidence so taken.*

*(3) If any person fails to pay an assessment of a civil penalty after the penalty has become a final and unappealable order, or after the appropriate court of appeals has entered a final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General. The Attorney General shall institute a civil action to recover the amount assessed in an appropriate district court of the United States. In the collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.*

*(4) All penalties collected under this subsection shall be paid into the Treasury of the United States.*

*(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty assessed under this subsection.*

*(6) Paragraph (1) shall not apply to an official plant.*

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–237 effective 12 months after promulgation of final implementing regulations, see section 1012(h) of Pub. L. 102–237, set out as a note under section 1034 of this title.

**§ 1042. Reporting of violation to United States attorney for institution of criminal proceedings; procedure; presentation of views**

Before any violation of this chapter is reported by the Secretary of Agriculture or Secretary of Health and Human Services to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given reasonable notice of the alleged violation and opportunity to present his views orally or in writing with regard to such contemplated proceeding. Nothing in this chapter shall be construed as requiring the Secretary of Agriculture or Secretary of Health and Human Services to report for criminal prosecution violations of this chapter whenever he believes that the public interest will be adequately served and compliance with this chapter obtained by a suitable written notice of warning.

(Pub. L. 91–597, § 13, Dec. 29, 1970, 84 Stat. 1628; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93

Stat. 695; Pub. L. 102–237, title X, § 1012(e), Dec. 13, 1991, 105 Stat. 1900.)

AMENDMENT OF SECTION

*Pub. L. 102–237, title X, § 1012(e), (h), Dec. 13, 1991, 105 Stat. 1900, 1901, provided that, effective 12 months after promulgation of final implementing regulations, this section is amended by inserting before the period at the end of the last sentence the following: ''or an action to assess civil penalties''.*

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted in text for ''Secretary of Health, Education, and Welfare'' pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–237 effective 12 months after promulgation of final implementing regulations, see section 1012(h) of Pub. L. 102–237, set out as a note under section 1034 of this title.

### § 1043. Rules and regulations; administration and enforcement

The Secretary shall promulgate such rules and regulations as he deems necessary to carry out the purposes or provisions of this chapter, and shall be responsible for the administration and enforcement of this chapter except as otherwise provided in section 1034(d) of this title.

(Pub. L. 91–597, § 14, Dec. 29, 1970, 84 Stat. 1629.)

### § 1044. Exemption of certain activities

#### (a) Regulation for exemptions

The Secretary may, by regulation and under such conditions and procedures as he may prescribe, exempt from specific provisions of this chapter—

(1) the sale, transportation, possession, or use of eggs which contain no more restricted eggs than are allowed by the tolerance in the official standards of United States consumer grades for shell eggs;

(2) the processing of egg products at any plant where the facilities and operating procedures meet such sanitary standards as may be prescribed by the Secretary, and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards of United States consumer grades for shell eggs, and the egg products processed at such plant;

(3) the sale of eggs by any poultry producer from his own flocks directly to a household consumer exclusively for use by such consumer and members of his household and his nonpaying guests and employees, and the transportation, possession, and use of such eggs in accordance with this paragraph;

(4) the processing of egg products by any poultry producer from eggs of his own flocks' production for sale of such products directly to a household consumer exclusively for use by such consumer and members of his household and his nonpaying guests and employees, and the egg products so processed when handled in accordance with this paragraph;

(5) the sale of eggs by shell egg packers on his own premises directly to household consumers for use by such consumer and members of his household and his nonpaying guests and employees, and the transportation, possession, and use of such eggs in accordance with this paragraph;

(6) for such period of time (not to exceed two years) during the initiation of operations under this chapter as the Secretary determines that it is impracticable to provide inspection, the processing of egg products at any class of plants and the egg products processed at such plants; and

(7) the sale of eggs by any egg producer with an annual egg production from a flock of three thousand or less hens.

#### (b) Plants located in noncontiguous areas of United States

The Secretary shall, by regulation and under such procedures as he may prescribe, exempt any plant located within noncontiguous areas of the United States from specific provisions of this chapter, where, despite good faith efforts by the owner of such plant, such owner has not been able to bring his plant into full compliance with this chapter: *Provided*, That in order to provide at least minimum standards for the protection of the public health, whenever processing operations are being conducted at any such plant, continuous inspection shall be maintained to assure that it is operated in a sanitary manner. No exemption under this subsection shall be granted for a period extending beyond December 31, 1971.

#### (c) Suspension or termination of exemptions

The Secretary may immediately suspend or terminate any exemption under subsection (a)(2) or (6) of this section at any time with respect to any person, if the conditions of exemption prescribed by this section or the regulations of the Secretary are not being met. The Secretary may modify or revoke any regulation granting exemption under this chapter whenever he deems such action appropriate to effectuate the purposes of this chapter.

(Pub. L. 91–597, § 15, Dec. 29, 1970, 84 Stat. 1629; Pub. L. 92–67, Aug. 6, 1971, 85 Stat. 173.)

AMENDMENTS

1971—Subsecs. (b), (c). Pub. L. 92–67 added subsec. (b) and redesignated former subsec. (b) as (c).

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1034 of this title.

### § 1045. Limitation on entry of eggs and egg products and other materials into official plants

The Secretary may limit the entry of eggs and egg products and other materials into official plants under such conditions as he may prescribe to assure that allowing the entry of such articles into such plants will be consistent with the purposes of this chapter.

(Pub. L. 91–597, § 16, Dec. 29, 1970, 84 Stat. 1630.)

### § 1046. Imports

**(a) Authorization for importation of restricted eggs; prerequisites for importation of egg products; treatment as domestic articles subject to this chapter; marking and labeling exemption for personal consumption**

No restricted eggs capable of use as human food shall be imported into the United States except as authorized by regulations of the Secretary. No egg products capable of use as human food shall be imported into the United States unless they were processed under an approved continuous inspection system of the government of the foreign country of origin or subdivision thereof and are labeled and packaged in accordance with, and otherwise comply with the standards of this chapter and regulations issued thereunder applicable to such articles within the United States. All such imported articles shall upon entry into the United States be deemed and treated as domestic articles subject to the other provisions of this chapter: *Provided*, That they shall be labeled as required by such regulations for imported articles: *Provided further*, That nothing in this section shall apply to eggs or egg products purchased outside the United States by any individual for consumption by him and members of his household and his nonpaying guests and employees.

**(b) Terms and conditions for destruction**

The Secretary may prescribe the terms and conditions for the destruction of all such articles which are imported contrary to this section, unless (1) they are exported by the consignee within the time fixed therefor by the Secretary or (2) in the case of articles which are not in compliance solely because of misbranding, such articles are brought into compliance with this chapter under supervision of authorized representatives of the Secretary.

**(c) Payment of storage, cartage, and labor charges by owner or consignee; liens**

All charges for storage, cartage, and labor with respect to any article which is imported contrary to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such article and any other article thereafter imported under this chapter by or for such owner or consignee.

**(d) Prohibition**

The importation of any article contrary to this section is prohibited.

(Pub. L. 91–597, § 17, Dec. 29, 1970, 84 Stat. 1630; Pub. L. 102–237, title X, § 1012(f), Dec. 13, 1991, 105 Stat. 1901.)

AMENDMENT OF SUBSECTION (a)

*Pub. L. 102–237, title X, § 1012(f), (h), Dec. 13, 1991, 105 Stat. 1901, provided that, effective 12 months after promulgation of final implementing regulations, subsection (a) of this section is amended:*

*(1) by designating the first, second, and third sentences as paragraphs (1), (2), and (4), respectively; and*

*(2) by inserting after paragraph (2) (as so designated) the following new paragraph:*

*(3) No eggs packed into a container that is destined for the ultimate consumer shall be imported into the United States unless the eggs are accompanied by a certification that the eggs have at all times after packaging been stored and transported under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit, as required by sections 1034(e) and 1037(c) of this title.*

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–237 effective 12 months after promulgation of final implementing regulations, see section 1012(h) of Pub. L. 102–237, set out as a note under section 1034 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1037, 1054 of this title.

### § 1047. Refusal or withdrawal of inspection services; hearing; grounds; person deemed to have responsible connection with business; finality of order of Secretary; judicial review; other provisions for refusal of services unaffected

The Secretary (for such period, or indefinitely, as he deems necessary to effectuate the purposes of this chapter) may refuse to provide or may withdraw inspection service under this chapter with respect to any plant if he determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection under this chapter because the applicant or recipient or anyone responsibly connected with the applicant or recipient has been convicted in any Federal or State court, within the previous ten years, of (1) any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food or fraud in connection with transactions in food, or (2) any felony, involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health.

For the purpose of this section, a person shall be deemed to be responsibly connected with the business if he is a partner, officer, director, holder, or owner of 10 per centum or more of its voting stock, or employee in a managerial or executive capacity.

The determination and order of the Secretary with respect thereto under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within thirty days after the effective date of such order in the United States court of appeals for the circuit in which such applicant or recipient has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Judicial review of any such order shall be upon the record upon which the determination and order are based. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

This section shall not affect in any way other provisions of this chapter for refusal of inspection services.

(Pub. L. 91–597, § 18, Dec. 29, 1970, 84 Stat. 1630.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1050 of this title.

### § 1048. Administrative detention of violative articles; duration; release; removal of official marks

Whenever any eggs or egg products subject to this chapter, are found by any authorized representative of the Secretary upon any premises and there is reason to believe that they are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of this chapter or that they are in any other way in violation of this chapter, or whenever any restricted eggs capable of use as human food are found by such a representative in the possession of any person not authorized to acquire such eggs under the regulations of the Secretary, such articles may be detained by such representative for a reasonable period but not to exceed twenty days, pending action under section 1049 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over such articles and shall not be moved by any person from the place at which they are located when so detained until released by such representative. All official marks may be required by such representative to be removed from such articles before they are released unless it appears to the satisfaction of the Secretary that the articles are eligible to retain such marks.

(Pub. L. 91–597, § 19, Dec. 29, 1970, 84 Stat. 1631.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1052 of this title.

### § 1049. Seizure and condemnation proceedings

#### (a) Jurisdiction; disposal of condemned articles; court costs and fees; conformity to supplemental rules for admiralty and maritime claims; jury trial; United States as plaintiff

Any eggs or egg products that are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation, in violation of this chapter, or in any other way are in violation of this chapter; and any restricted eggs, capable of use as human food, in the possession of any person not authorized to acquire such eggs under the regulations of the Secretary shall be liable to be proceeded against and seized and condemned, at any time, on a complaint in any United States district court or other proper court as provided in section 1050 of this title within the jurisdiction of which the articles are found. If the articles are condemned they shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the articles shall not be sold contrary to the provision of this chapter, the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the Fair Packaging and Labeling Act [15 U.S.C. 1451 et seq.], or the laws of the jurisdiction in which they are sold: *Provided*, That upon the execution and delivery of a good and sufficient bond conditioned that the articles shall not be sold or otherwise disposed of contrary to the provisions of this chapter, the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, or the laws of the jurisdiction in which disposal is made, the court may direct that they be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws. When a decree of condemnation is entered against the articles and they are released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant thereof. The proceedings in such cases shall conform, as nearly as may be, to the supplemental rules for certain admiralty and maritime claims, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

#### (b) Condemnation or seizure under other provisions unaffected

The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

(Pub. L. 91–597, § 20, Dec. 29, 1970, 84 Stat. 1631.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

The Fair Packaging and Labeling Act, referred to in subsec. (a), is Pub. L. 89–755, Nov. 3, 1966, 80 Stat. 1296, as amended, which is classified generally to chapter 39 (§ 1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1451 of Title 15 and Tables.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1048 of this title.

### § 1050. Jurisdiction of district courts; United States as plaintiff in enforcement and restraining proceedings; subpenas for witnesses

The United States district courts and the District Court of the Virgin Islands are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other cases, arising under this chapter, except as provided in section 1047 of this title. All proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States. Subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

(Pub. L. 91–597, § 21, Dec. 29, 1970, 84 Stat. 1632.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1049, 1051 of this title.

### § 1051. Other Federal laws applicable for administration and enforcement of chapter; prosecution of inquiries; exercise of jurisdiction

For the efficient administration and enforcement of this chapter, the provisions (including

penalties) of sections 46, 48, 49, and 50 of title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49[1] of title 15), and the provisions of section 409(*l*)[1] of title 47, are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of title 15, on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 1050 of this title.

(Pub. L. 91–597, § 22, Dec. 29, 1970, 84 Stat. 1632.)

REFERENCES IN TEXT

The last paragraph of section 49 of title 15, and the provisions of section 409(*l*) of title 47, referred to in text, which related to immunity of witnesses, were repealed by sections 211 and 242, respectively, of Pub. L. 91–452, Oct. 15, 1970, title II, 84 Stat. 929, 930. For provisions relating to immunity of witnesses, see section 6001 et seq. of Title 18, Crimes and Criminal Procedure.

**§ 1052. State or local regulation**

**(a) Prohibition against additional or different requirements than Federal requirements relating to premises, facilities, and operations at official plants; authority to impose recordkeeping and related requirements consistent with Federal requirements**

Requirements within the scope of this chapter with respect to premises, facilities, and operations of any official plant which are in addition to or different than those made under this chapter may not be imposed by any State or local jurisdiction except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 1040 of this title, if consistent therewith, with respect to any such plant.

**(b) Prohibition against additional or different standards than Federal standards of quality, etc., or requiring labeling to show area of production or origin; authority to require name, address, and license number of processor or packer on containers; prohibition against additional or different requirements than Federal requirements relating to labeling, packaging or ingredients; authority to prevent distribution of violative articles; validity of nonconflicting laws**

For eggs which have moved or are moving in interstate or foreign commerce, (1) no State or local jurisdiction may require the use of standards of quality, condition, weight, quantity, or grade which are in addition to or different from the official Federal standards, and (2) no State or local jurisdiction other than those in noncontiguous areas of the United States may require labeling to show the State or other geographical area of production or origin: *Provided, however*, That this shall not preclude a State from requiring that the name, address, and license number of the person processing or packaging eggs, be shown on each container. Labeling, packaging, or ingredient requirements, in addition to or different than those made under this chapter, the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and the Fair Packaging and Labeling Act [15 U.S.C. 1451 et seq.], may not be imposed by any State or local jurisdiction, with respect to egg products processed at any official plant in accordance with the requirements under this chapter and such Acts. However, any State or local jurisdiction may exercise jurisdiction with respect to eggs and egg products for the purpose of preventing the distribution for human food purposes of any such articles which are outside of such a plant and are in violation of any of said Federal Acts or any State or local law consistent therewith. Otherwise the provisions of this chapter shall not invalidate any law or other provisions of any State or other jurisdiction in the absence of a conflict with this chapter.

**(c) Applicability of other Federal laws and authority of other Federal officials relating to eggs, egg products, or other food products unaffected; authority of Secretary of Agriculture to regulate official plants processing egg products**

The provisions of this chapter shall not affect the applicability of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the Fair Packaging and Labeling Act [15 U.S.C. 1451 et seq.] or other Federal laws to eggs, egg products, or other food products or diminish any authority conferred on the Secretary of Health and Human Services or other Federal officials by such other laws, except that the Secretary of Agriculture shall have exclusive jurisdiction to regulate official plants processing egg products and operations thereof as to all matters within the scope of this chapter.

**(d) Detainer authority**

The detainer authority conferred on representatives of the Secretary of Agriculture by section 1048 of this title shall also apply to any authorized representative of the Secretary of Health and Human Services for the purposes of section 1034(d) of this title, with respect to any eggs or egg products that are outside any plant processing egg products.

(Pub. L. 91–597, § 23, Dec. 29, 1970, 84 Stat. 1632; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–237, title X, § 1012(g), Dec. 13, 1991, 105 Stat. 1901.)

AMENDMENT OF SUBSECTION (b)

*Pub. L. 102–237, title X, § 1012(g), (h), Dec. 13, 1991, 105 Stat. 1901, provided that, effective 12 months after promulgation of final implementing regulations, the first sentence of subsection (b) of this section is amended by striking ''and (2)'' and inserting the following: ''(2) with respect to egg handlers specified in paragraphs (1) and (2) of section 1034(e) of this title, no State or local jurisdiction may impose temperature requirements pertaining to eggs packaged for the ultimate consumer which are in addition to, or different from, Federal requirements, and (3)''.*

[1] See References in Text note below.

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b) and (c), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

The Fair Packaging and Labeling Act, referred to in subsecs. (b) and (c), is Pub. L. 89–755, Nov. 3, 1966, 80 Stat. 1296, as amended, which is classified generally to chapter 39 (§ 1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1451 of Title 15 and Tables.

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsecs. (c) and (d) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–237 effective 12 months after promulgation of final implementing regulations, see section 1012(h) of Pub. L. 102–237, set out as a note under section 1034 of this title.

### § 1053. Inspection and administration costs

#### (a) Overtime and holiday work costs; availability of funds

The cost of inspection rendered under the requirements of this chapter, and other costs of administration of this chapter, shall be borne by the United States, except that the cost of overtime and holiday work performed in official plants subject to the provisions of this chapter at such rates as the Secretary may determine shall be borne by such official plants. Sums received by the Secretary from official plants under this section shall be available without fiscal year limitation to carry out the purposes of this chapter.

#### (b) "Holiday" defined

The term ''holiday'' for the purposes of assessment or reimbursement of the cost of inspection performed under this chapter, the Wholesome Poultry Products Act [21 U.S.C. 467a et seq.] and the Wholesome Meat Act [21 U.S.C. 601 et seq.] shall mean the legal public holidays specified by the Congress in section 6103(a) of title 5.

(Pub. L. 91–597, § 24, Dec. 29, 1970, 84 Stat. 1633.)

REFERENCES IN TEXT

The Wholesome Poultry Products Act, referred to in subsec. (b), is Pub. L. 90–492, Aug. 18, 1968, 82 Stat. 791, as amended, which enacted sections 467a to 467f and 470 of this title, amended sections 451 to 461, 463 to 465, and 467 of this title, and enacted provisions set out as notes under section 451 of this title. For complete classification of this Act to the Code, see Short Title of 1968 Amendment note set out under section 451 of this title and Tables.

The Wholesome Meat Act, referred to in subsec. (b), is Pub. L. 90–201, Dec. 15, 1967, 81 Stat. 584, as amended, which enacted sections 601, 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amended sections 603 to 623 of this title, repealed section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacted provisions set out as notes under section 601 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

### § 1054. Annual report to Congressional committees

Not later than March 1 of each year following December 29, 1970, the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a comprehensive and detailed written report with respect to—

(1) the processing, storage, handling, and distribution of eggs and egg products subject to the provisions of this chapter; the inspection of establishments operated in connection therewith; the effectiveness of the operations of the inspection, including the effectiveness of the operations of State egg inspection programs; and recommendations for legislation to improve such program; and

(2) the administration of section 1046 of this title (relating to imports) during the immediately preceding calendar year, including but not limited to—

(A) a certification by the Secretary that foreign plants exporting eggs or egg products to the United States have complied with requirements of this chapter and regulations issued thereunder;

(B) the names and locations of plants authorized or permitted to export eggs or egg products to the United States;

(C) the number of inspectors employed by the Department of Agriculture in the calendar year concerned who were assigned to inspect plants referred to in paragraph (B) hereof and the frequency with which each such plant was inspected by such inspectors;

(D) the number of inspectors that were licensed by each country from which any imports were received and that were assigned, during the calendar year concerned, to inspect such imports and the facilities in which such imports were handled; and the frequency and effectiveness of such inspections;

(E) the total volume of eggs and egg products which was imported into the United States during the calendar year concerned from each country, including a separate itemization of the volume of each major category of such imports from each country during such year, and a detailed report of rejections of plants and products because of failure to meet appropriate standards prescribed by this chapter; and

(F) recommendations for legislation to improve such program.

(Pub. L. 91–597, § 26, Dec. 29, 1970, 84 Stat. 1634; Pub. L. 103–437, § 8(4), Nov. 2, 1994, 108 Stat. 4588.)

AMENDMENTS

1994—Pub. L. 103–437 substituted ''Agriculture, Nutrition, and Forestry'' for ''Agriculture and Forestry'' in introductory provisions.

### § 1055. Authorization of appropriations

Such sums as are necessary to carry out the provisions of this chapter are hereby authorized to be appropriated.

(Pub. L. 91–597, § 27, Dec. 29, 1970, 84 Stat. 1635.)

### § 1056. Separability

If any provision of this chapter or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the chapter and of the application of such provision to other persons and circumstances shall not be affected thereby.

(Pub. L. 91–597, § 28, Dec. 29, 1970, 84 Stat. 1635.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original ''this Act'', meaning Pub. L. 91–597, Dec. 29, 1970, 84 Stat. 1620, as amended, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables.

## CHAPTER 16—DRUG ABUSE PREVENTION, TREATMENT, AND REHABILITATION

SUBCHAPTER I—GENERAL PROVISIONS

Sec.
1101. Congressional findings.
1102. Congressional declaration of national policy.
1103, 1104. Repealed.

SUBCHAPTER II—DRUG ABUSE POLICY COORDINATION

1111 to 1114. Repealed.
1115. Notice relating to the control of dangerous drugs.
1116 to 1155. Repealed or Omitted.

SUBCHAPTER III—NATIONAL DRUG ABUSE STRATEGY

1161 to 1165. Repealed.

SUBCHAPTER IV—OTHER FEDERAL PROGRAMS

1171. Drug abuse prevention function appropriations.
1172 to 1176. Repealed, Transferred, or Omitted.
1177. Special project grants and contracts.
(a) Scope of programs; priority.
(b) Authorization of appropriations.
(c) Coordination of applications for programs in a State; precedence restriction; project evaluation; application approval; criteria; proposed performance standards or research protocol.
(d) Programs and projects aimed at underserved groups; encouragement and special consideration given to applications.
(e) Payments; advances; reimbursement; installments.
(f) Prevention and treatment services.
(g) Authorization by chief executive officer of State required; maximum amount and duration of grants.
1178. Records and audit.
(a) Assistance records; contents.
(b) Access to pertinent information for audit and examination.
1179. National Drug Abuse Training Center.
(a) Establishment; functions; general policies; transfer of supervision.
(b) Activities and material.
(c) Persons eligible for services and facilities.
(d) Authorization of appropriations; fiscal year availability.
1180. Transferred.
1181. Contract authority.

SUBCHAPTER V—NATIONAL INSTITUTE ON DRUG ABUSE

1191 to 1194. Transferred or Repealed.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in title 38 section 7334.

SUBCHAPTER I—GENERAL PROVISIONS

### § 1101. Congressional findings

The Congress makes the following findings:

(1) Drug abuse is rapidly increasing in the United States and now afflicts urban, suburban, and rural areas of the Nation.

(2) Drug abuse seriously impairs individual, as well as societal, health and well-being.

(3) Drug abuse, especially heroin addiction, substantially contributes to crime.

(4) The adverse impact of drug abuse inflicts increasing pain and hardship on individuals, families, and communities and undermines our institutions.

(5) Too little is known about drug abuse, especially the causes, and ways to treat and prevent drug abuse.

(6) The success of Federal drug abuse programs and activities requires a recognition that education, treatment, rehabilitation, research, training, and law enforcement efforts are interrelated.

(7) The effectiveness of efforts by State and local governments and by the Federal Government to control and treat drug abuse in the United States has been hampered by a lack of coordination among the States, between States and localities, among the Federal Government, States and localities, and throughout the Federal establishment.

(8) Control of drug abuse requires the development of a comprehensive, coordinated long-term Federal strategy that encompasses both effective law enforcement against illegal drug traffic and effective health programs to rehabilitate victims of drug abuse.

(9) The increasing rate of drug abuse constitutes a serious and continuing threat to national health and welfare, requiring an immediate and effective response on the part of the Federal Government.

(10) Although the Congress observed a significant apparent reduction in the rate of increase of drug abuse during the three-year period subsequent to March 21, 1972, and in certain areas of the country apparent temporary reductions in its incidence, the increase and spread of heroin consumption since 1974, and the continuing abuse of other dangerous drugs, clearly indicate the need for effective, ongoing, and highly visible Federal leadership in the formation and execution of a comprehensive, coordinated drug abuse policy.

(11) Shifts in the usage of various drugs and in the Nation's demographic composition require a Federal strategy to adjust the focus of drug abuse programs to meet new needs and priorities on a cost-effective basis.

(12) The growing extent of drug abuse indicates an urgent need for prevention and intervention programs designed to reach the general population and members of high risk populations such as youth, women, and the elderly.

(13) Effective control of drug abuse requires high-level coordination of Federal international and domestic activities relating to

both supply of, and demand for, commonly abused drugs.

(14) Local governments with high concentrations of drug abuse should be actively involved in the planning and coordination of efforts to combat drug abuse.

(Pub. L. 92–255, title I, § 101, Mar. 21, 1972, 86 Stat. 66; Pub. L. 94–237, § 1, Mar. 19, 1976, 90 Stat. 241; Pub. L. 96–181, § 2, Jan. 2, 1980, 93 Stat. 1309.)

AMENDMENTS

1980—Pars. (11) to (14). Pub. L. 96–181 added pars. (11) to (14).

1976—Par. (10). Pub. L. 94–237 added par. (10).

SHORT TITLE OF 1980 AMENDMENT

Section 1(a) of Pub. L. 96–181 provided that: ''This Act [enacting sections 1111 to 1117 and 1181 of this title, amending this section, sections 1102, 1162, 1164, 1176, 1177, 1180, and 1191 to 1193 of this title, and sections 218, 300*l*–2, 300m–3, and 3733 of Title 42, The Public Health and Welfare, omitting sections 1118 to 1120 and 1131 to 1133 of this title, enacting provisions set out as notes under this section and section 1193 of this title, and amending provisions set out as a note below] may be cited as the 'Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979'.''

SHORT TITLE OF 1978 AMENDMENT

Pub. L. 95–461, § 1, Oct. 14, 1978, 92 Stat. 1268, provided that: ''This Act [enacting section 1194 of this title, amending sections 1172, 1176, 1177, 1192, and 1193 of this title, enacting a provision set out as a note under section 1172 of this title and amending a provision set out as a note under section 242 of Title 42, The Public Health and Welfare] may be cited as the 'Drug Abuse Prevention and Treatment Amendments of 1978'.''

SHORT TITLE

Section 1 of Pub. L. 92–255, as amended by Pub. L. 96–181, § 15(a), Jan. 2, 1980, 93 Stat. 1316, provided that: ''This Act [enacting this chapter, and amending sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n–1, and 2688t of Title 42, The Public Health and Welfare] may be cited as the 'Drug Abuse Prevention, Treatment, and Rehabilitation Act'.''

REFERENCES TO DRUG ABUSE OFFICE AND TREATMENT ACT OF 1972

Section 15(b) of Pub. L. 96–181 provided in part that: ''Whenever reference is made in any other Federal law, regulation, ruling, or order to the Drug Abuse Office and Treatment Act of 1972, the reference shall be considered to be made to the Drug Abuse Prevention, Treatment, and Rehabilitation Act.''

### § 1102. Congressional declaration of national policy

The Congress declares that it is the policy of the United States and the purpose of this chapter to focus the comprehensive resources of the Federal Government and bring them to bear on drug abuse with the objective of significantly reducing the incidence, as well as the social and personal costs, of drug abuse in the United States, and to develop and assure the implementation of a comprehensive, coordinated long-term Federal strategy to combat drug abuse. To reach these goals, the Congress further declares that it is the policy of the United States and the purpose of this chapter to meet the problems of drug abuse through—

(1) comprehensive Federal, State, and local planning for, and effective use of, Federal assistance to States and to community-based programs to meet the urgent needs of special populations, in coordination with all other governmental and nongovernmental sources of assistance;

(2) the development and support of community-based prevention programs;

(3) the development and encouragement of effective occupational prevention and treatment programs within the Government and in cooperation with the private sector; and

(4) increased Federal commitment to research into the behavioral and biomedical etiology of, the treatment of, and the mental and physical health and social and economic consequences of, drug abuse.

(Pub. L. 92–255, title I, § 102, Mar. 21, 1972, 86 Stat. 66; Pub. L. 94–237, § 2, Mar. 19, 1976, 90 Stat. 241; Pub. L. 96–181, § 3, Jan. 2, 1980, 93 Stat. 1309.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original ''this Act'', meaning Pub. L. 92–255, Mar. 21, 1972, 86 Stat. 65, as amended, known as the Drug Abuse Prevention, Treatment, and Rehabilitation Act, which comprises this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 1101 of this title and Tables.

AMENDMENTS

1980—Pub. L. 96–181 inserted additional declarations of policy prescribing methods and programs by which the goals are to be reached.

1976—Pub. L. 94–237 substituted ''objective of significantly reducing the incidence, as well as the social and personal costs, of drug abuse in the United States, and to develop and assure the implementation of'' for ''immediate objective of significantly reducing the incidence of drug abuse in the United States within the shortest possible period of time, and to develop''.

### § 1103. Repealed. Pub. L. 100–690, title I, § 1007(c)(1), Nov. 18, 1988, 102 Stat. 4187

Section, Pub. L. 92–255, title I, § 103, Mar. 21, 1972, 86 Stat. 67; Pub. L. 94–237, §§ 3, 4(a), Mar. 19, 1976, 90 Stat. 241, defined ''drug abuse prevention function'', ''drug traffic prevention function'', and ''drug abuse function''.

EFFECTIVE DATE OF REPEAL

Repeal effective Jan. 21, 1989, see section 1012 of Pub. L. 100–690, set out as an Effective Date note under section 1501 of this title.

### § 1104. Repealed. Pub. L. 94–237, § 4(c)(1), Mar. 19, 1976, 90 Stat. 244

Section, Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, provided, effective June 30, 1975, that the Special Action Office for Drug Abuse Prevention, each of the positions in the Office of Director, Deputy Director, and Assistant Director, and the National Advisory Council for Drug Abuse Prevention were abolished and former subchapter II of this chapter was repealed.

## SUBCHAPTER II—DRUG ABUSE POLICY COORDINATION

### §§ 1111 to 1114. Repealed. Pub. L. 100–690, title I, § 1007(c)(1), Nov. 18, 1988, 102 Stat. 4187

Section 1111, Pub. L. 92–255, title II, § 201, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1310; amended Pub. L. 98–473, title II, § 1306, Oct. 12, 1984, 98 Stat. 2170, related to concentration of Federal effort in drug abuse prevention.

A prior section 1111, Pub. L. 92–255, title II, § 201, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 242, which provided for the establishment of the Office of Drug Abuse Policy, was omitted in the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309. Previously, the Office of Drug Abuse Policy was abolished and the functions of the Office and its Director were transferred to the President by sections 3 and 5 of Reorg. Plan No. 1 of 1977, effective Mar. 27, 1978, as provided by Ex. Ord. No. 12045, Mar. 27, 1978, 43 F.R. 13347, set out as notes preceding section 101 of Title 3, The President.

Another prior section 1111, Pub. L. 92–255, title II, § 201, Mar. 21, 1972, 86 Stat. 67, which provided for the establishment of the Special Action Office for Drug Abuse Prevention, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Section 1112, Pub. L. 92–255, title II, § 202, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1310, related to designation of a representative to direct activities required by this subchapter.

A prior section 1112, Pub. L. 92–255, title II, § 202, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 242; amended Pub. L. 95–83, title III, § 311(d), Aug. 1, 1977, 91 Stat. 398, which provided for the appointment of the Director of the Office of Drug Abuse Policy, was omitted in the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

Another prior section 1112, Pub. L. 92–255, title II, § 202, Mar. 21, 1972, 86 Stat. 68, which provided for the appointment of a Director of the Special Action Office for Drug Abuse Prevention, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Section 1113, Pub. L. 92–255, title II, § 203, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1310, related to employment of officers and employees.

A prior section 1113, Pub. L. 92–255, title II, § 203, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 242, which provided for the appointment and functions of Deputy Director of the Office of Drug Abuse Policy, was omitted in the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

Another prior section 1113, Pub. L. 92–255, title II, § 203, Mar. 21, 1972, 86 Stat. 68, which provided for the appointment of a Deputy Director of the Special Office for Drug Abuse Prevention, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Section 1114, Pub. L. 92–255, title II, § 204, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1310, related to acceptance of uncompensated services.

A prior section 1114, Pub. L. 92–255, title II, § 204, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 242, which provided for the delegation of functions by the Director of the Office of Drug Abuse Policy, was omitted in the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

Another prior section 1114, Pub. L. 92–255, title II, § 204, Mar. 21, 1972, 86 Stat. 68, which provided for the appointment of six Assistant Directors, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Provisions similar to this section were contained in section 1117 of this title prior to the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

EFFECTIVE DATE OF REPEAL

Repeal effective Jan. 21, 1989, see section 1012 of Pub. L. 100–690, set out as an Effective Date note under section 1501 of this title.

EXECUTIVE ORDER NO. 12368

Ex. Ord. No. 12368, June 24, 1982, 47 F.R. 27843, as amended by Ex. Ord. No. 12590, Mar. 26, 1987, 52 F.R. 10021, related to assignment of drug abuse policy functions.

## § 1115. Notice relating to the control of dangerous drugs

Whenever the Attorney General determines that there is evidence that—

(1) a drug or other substance, which is not a controlled substance (as defined in section 802(6) of this title), has a potential for abuse, or

(2) a controlled substance should be transferred or removed from a schedule under section 812 of this title,

he shall, prior to initiating any proceeding under section 811(a) of this title, give the President timely notice of such determination. Information forwarded to the Attorney General pursuant to section 811(f) of this title shall also be forwarded by the Secretary of Health and Human Services to the President.

(Pub. L. 92–255, title II, § 201, formerly § 205, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1311; amended Pub. L. 97–35, title IX, § 973(a), Aug. 13, 1981, 95 Stat. 598; renumbered § 201, Pub. L. 100–690, title I, § 1007(c)(1), Nov. 18, 1988, 102 Stat. 4187.)

PRIOR PROVISIONS

A prior section 201 of Pub. L. 92–255, title II, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1310; amended Pub. L. 98–473, title II, § 1306, Oct. 12, 1984, 98 Stat. 2170, related to concentration of Federal effort in drug abuse prevention, prior to repeal by Pub. L. 100–690, title I, § 1007(c)(1), Nov. 18, 1988, 102 Stat. 4187.

A prior section 1115, Pub. L. 92–255, title II, § 205, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 242, which provided for employment, functions, and travel expenses of employees, was omitted in the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

Another prior section 1115, Pub. L. 92–255, title II, § 205, Mar. 21, 1972, 86 Stat. 68, provided for the delegation of functions by the Director, prior to repeal by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Provisions similar to this section were contained in section 1118 of this title prior to the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

AMENDMENTS

1981—Pub. L. 97–35 substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

## § 1116. Repealed. Pub. L. 100–690, title I, § 1007(c)(1), Nov. 18, 1988, 102 Stat. 4187

Section, Pub. L. 92–255, title II, § 206, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1311, provided that this subchapter not be construed as limiting the statutory authority of the Secretary of Defense or the Administrator of Veterans' Affairs.

EFFECTIVE DATE OF REPEAL

Repeal effective Jan. 21, 1989, see section 1012 of Pub. L. 100–690, set out as an Effective Date note under section 1501 of this title.

A prior section 1116, Pub. L. 92–255, title II, § 206, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 242, which provided for the employment and compensation of experts and consultants, was omitted in the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

Another prior section 1116, Pub. L. 92–255, title II, § 206, Mar. 21, 1972, 86 Stat. 68, which provided for the employment and prescription of functions for officers and employees by the Director, was repealed by Pub. L.

92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Provisions similar to this section were contained in section 1119 of this title prior to the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

### § 1117. Repealed. Pub. L. 98–24, § 4(b), Apr. 26, 1983, 97 Stat. 183

Section, Pub. L. 92–255, title II, § 207, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1311, required the President to make annual reports to the Congress on the drug abuse prevention activities under this subchapter. See section 290aa–4 of Title 42, The Public Health and Welfare.

A prior section 1117, Pub. L. 92–255, title II, § 207, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 243, which provided for acceptance of uncompensated services, was omitted in the general revision of this subchapter by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

Another prior section 1117, Pub. L. 92–255, title II, § 207, Mar. 21, 1972, 86 Stat. 68, which provided for the procurement of experts and consultants by the Director, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

### §§ 1118 to 1120. Omitted

CODIFICATION

Section 1118, Pub. L. 92–255, title II, § 208, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 243, which related to giving of notice to Director prior to initiation of a section 811(a) proceeding, was omitted in the general revision of title II of Pub. L. 92–255 by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309. See section 1115 of this title.

A prior section 1118, Pub. L. 92–255, title II, § 208, Mar. 21, 1972, 86 Stat. 68, which provided for acceptance of uncompensated services by Director, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Section 1119, Pub. L. 92–255, title II, § 210, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 243, which related to effect of this subchapter on statutory requirements and authorities, was omitted in the general revision of title II of Pub. L. 92–255 by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309. See section 1116 of this title.

A prior section 1119, Pub. L. 92–255, title II, § 209, Mar. 21, 1972, 86 Stat. 68, which provided for notice by Attorney General to Director with respect to control of dangerous drugs, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

A prior section 210 of Pub. L. 92–255, title II, Mar. 21, 1972, 86 Stat. 69, which provided for authority of Director to make grants and enter into contract, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Section 1120, Pub. L. 92–255, title II, § 211, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 243, which related to authorization of appropriations with regard to this subchapter, was omitted in the general revision of title II of Pub. L. 92–255 by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309.

A prior section 1120, Pub. L. 92–255, title II, § 210, Mar. 21, 1972, 86 Stat. 69, which provided for authority of Director to make grants and enter into contracts, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

A prior section 211 of Pub. L. 92–255, title II, Mar. 21, 1972, 86 Stat. 69, which provided for appointment of an acting Director until position was initially filled, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

### §§ 1121 to 1123. Repealed. Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67

Section 1121, Pub. L. 92–255, title II, § 211, Mar. 21, 1972, 86 Stat. 69, provided for appointment of an acting Director until position was initially filled.

Section 1122, Pub. L. 92–255, title II, § 213, Mar. 21, 1972, 86 Stat. 69, prohibited Director or any other Federal officer from waiving or disregarding any limitation or requirement prescribed by law with respect to any Federal program or activity.

Section 1123, Pub. L. 92–255, title II, § 214, Mar. 21, 1972, 86 Stat. 70, provided for authorization of appropriations, and fiscal year availability of such appropriations.

EFFECTIVE DATE OF REPEAL

Section 1104 of this title, prior to repeal by section 4(c)(1) of Pub. L. 94–237, provided for repeal of sections effective June 30, 1975.

### §§ 1131 to 1133. Omitted

CODIFICATION

Section 1131, Pub. L. 92–255, title II, § 221, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 243, which related to functions of Director concerning planning and policies, was omitted in the general revision of title II of Pub. L. 92–255 by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309. See section 1111 of this title.

A prior section 1131, Pub. L. 92–255, title II, § 221, Mar. 21, 1972, 86 Stat. 70, which provided for establishment of overall planning and policy and the criteria to achieve objectives and priorities for all Federal drug abuse prevention functions, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Section 1132, Pub. L. 92–255, title II, § 222, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 243, which authorized President to designate Director to represent United States in negotiations concerning drug abuse functions, was omitted in the general revision of title II of Pub. L. 92–255 by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309. See section 1112 of this title.

A prior section 1132, Pub. L. 92–255, title II, § 222, Mar. 21, 1972, 86 Stat. 71, which provided for review and modification of implementation plans and budget requests, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

Section 1133, Pub. L. 92–255, title II, § 223, as added Pub. L. 94–237, § 4(b), Mar. 19, 1976, 90 Stat. 244, which related to an annual report to President and Congress on activities of Office of Drug Abuse Policy, was omitted in the general revision of title II of Pub. L. 92–255 by Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1309. See section 1117 of this title.

A prior section 1133, Pub. L. 92–255, title II, § 223, Mar. 21, 1972, 86 Stat. 71, which provided for establishment and the objectives of a Special Fund, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

### §§ 1134 to 1143. Repealed. Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67

Section 1134, Pub. L. 92–255, title II, § 224, Mar. 21, 1972, 86 Stat. 71, provided for establishment of research and development programs by Director.

Section 1135, Pub. L. 92–255, title II, § 225, Mar. 21, 1972, 86 Stat. 72, provided for establishment of a single non-Federal share requirement.

Section 1136, Pub. L. 92–255, title II, § 226, Mar. 21, 1972, 86 Stat. 72, provided for Director to make drug prevention function recommendations to President and to consult with responsible agencies with respect to drug prevention functions.

Section 1137, Pub. L. 92–255, title II, § 227, Mar. 21, 1972, 86 Stat. 72, provided for resolution of agency conflicts with regard to drug prevention functions.

Section 1138, Pub. L. 92–255, title II, § 228, Mar. 21, 1972, 86 Stat. 72, provided for communications and liaison with respect to drug prevention functions by one of Assistant Directors.

Section 1139, Pub. L. 92–255, title II, § 229, Mar. 21, 1972, 86 Stat. 72, provided, with respect to drug prevention functions, coordination of State and local govern-

ments, availability of information and other services and activities.

Section 1140, Pub. L. 92–255, title II, § 230, Mar. 21, 1972, 86 Stat. 73, provided for a management oversight review by a Federal officer.

Section 1141, Pub. L. 92–255, title II, § 231, Mar. 21, 1972, 86 Stat. 73, provided for convening of a council of officials of Federal agencies responsible for drug prevention functions by Director.

Section 1142, Pub. L. 92–255, title II, § 232, Mar. 21, 1972, 86 Stat. 73, provided for designation of the Director to represent Government in international negotiations related to drug prevention functions.

Section 1143, Pub. L. 92–255, title II, § 233, Mar. 21, 1972, 86 Stat. 73, provided for an annual written report to the President by the Director.

EFFECTIVE DATE OF REPEAL

Section 1104 of this title, prior to repeal by section 4(c)(1) of Pub. L. 94–237, provided for repeal of sections effective June 30, 1975.

### §§ 1151 to 1155. Repealed. Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67

Section 1151, Pub. L. 92–255, title II, § 251, Mar. 21, 1972, 86 Stat. 74, provided for establishment of a National Advisory Council for Drug Abuse Prevention.

Section 1152, Pub. L. 92–255, title II, § 252, Mar. 21, 1972, 86 Stat. 74, provided for membership of National Advisory Council for Drug Abuse Prevention.

Section 1153, Pub. L. 92–255, title II, § 253, Mar. 21, 1972, 86 Stat. 74, provided for designation of chairman of National Advisory Council for Drug Abuse Prevention.

Section 1154, Pub. L. 92–255, title II, § 254, Mar. 21, 1972, 86 Stat. 74, provided for compensation and expenses for members of National Advisory Council for Drug Abuse Prevention.

Section 1155, Pub. L. 92–255, title II, § 255, Mar. 21, 1972, 86 Stat. 74, set forth functions of National Advisory Council for Drug Abuse Prevention.

EFFECTIVE DATE OF REPEAL

Section 1104 of this title, prior to repeal by section 4(c)(1) of Pub. L. 94–237, provided for repeal of sections effective June 30, 1975.

## SUBCHAPTER III—NATIONAL DRUG ABUSE STRATEGY

### §§ 1161 to 1165. Repealed. Pub. L. 98–509, title III, § 301(d), Oct. 19, 1984, 98 Stat. 2364

Section 1161, Pub. L. 92–255, title III, § 301, Mar. 21, 1972, 86 Stat. 74, related to development, and initial promulgation no later than nine months after Mar. 21, 1972, by the President, of a national drug abuse strategy.

Section 1162, Pub. L. 92–255, title III, § 302, Mar. 21, 1972, 86 Stat. 75; Pub. L. 94–237, § 4(c)(2), (3), (5)(A), Mar. 19, 1976, 90 Stat. 244; Pub. L. 96–181, § 5(a), (b), Jan. 2, 1980, 93 Stat. 1311; Pub. L. 97–35, title IX, § 973(b), Aug. 13, 1981, 95 Stat. 598, related to establishment and membership of a Strategy Council, interim provision of services by the Director, and review and commentary on the national drug abuse strategy by those Federal officials participating in its preparation.

Section 1163, Pub. L. 92–255, title III, § 303, Mar. 21, 1972, 86 Stat. 75, related to contents of the national drug abuse strategy.

Section 1164, Pub. L. 92–255, title III, § 304, Mar. 21, 1972, 86 Stat. 75; Pub. L. 94–237, § 4(c)(4), Mar. 19, 1976, 90 Stat. 244; Pub. L. 96–181, § 5(c), Jan. 2, 1980, 93 Stat. 1311, related to preparation of the national drug abuse strategy.

Section 1165, Pub. L. 92–255, title III, § 305, Mar. 21, 1972, 86 Stat. 75; Pub. L. 94–237, § 5, Mar. 19, 1976, 90 Stat. 244; Pub. L. 98–24, § 4(a), Apr. 26, 1983, 97 Stat. 183, related to submission by the President to the Congress, on or before Aug. 1, 1984, and every two years thereafter, of a written report describing the national drug abuse strategy, and prescribed the contents of the report.

## SUBCHAPTER IV—OTHER FEDERAL PROGRAMS

### § 1171. Drug abuse prevention function appropriations

Any request for appropriations by a department or agency of the Government submitted after March 21, 1972, shall specify (1) on a line item basis, that part of the appropriations which the department or agency is requesting to carry out its drug abuse prevention functions, and (2) the authorization of the appropriations requested to carry out each of its drug abuse prevention functions.

(Pub. L. 92–255, title IV, § 404, Mar. 21, 1972, 86 Stat. 77.)

### § 1172. Repealed. Pub. L. 98–24, § 2(c)(2), Apr. 26, 1983, 97 Stat. 182

Section, Pub. L. 92–255, title IV, § 405, Mar. 21, 1972, 86 Stat. 77; Pub. L. 95–461, § 3(b), Oct. 14, 1978, 92 Stat. 1268; Pub. L. 97–35, title IX, § 973(c)(1), Aug. 13, 1981, 95 Stat. 598, required that the Secretary of Health and Human Services make periodic reports to the Congress and to the President on drug abuse in the United States. See section 290aa–4 of Title 42, The Public Health and Welfare.

### § 1173. Transferred and Omitted

Section, Pub. L. 92–255, title IV, § 406, Mar. 21, 1972, 86 Stat. 78; Pub. L. 97–35, title IX, § 968(a), Aug. 13, 1981, 95 Stat. 595, established additional drug abuse prevention functions of the Secretary of Health and Human Services.

Subsec. (a) was redesignated as section 503(e) of the Public Health Service Act by Pub. L. 98–24, § 2(b)(5), Apr. 26, 1983, 97 Stat. 177, and is classified to section 290aa–2(e) of Title 42, The Public Health and Welfare.

Subsec. (b), which directed that the Secretary carry out his functions under subsec. (a) of this section through the National Institute on Drug Abuse, was omitted.

### §§ 1174, 1175. Transferred

Section 1174, Pub. L. 92–255, title IV, § 407, Mar. 21, 1972, 86 Stat. 78; Pub. L. 94–237, § 6(a), Mar. 19, 1976, 90 Stat. 244; Pub. L. 94–581, title I, § 111(c)(2), Oct. 21, 1976, 90 Stat. 2852, which prohibited discrimination against drug abusers by general hospitals, was redesignated section 526 of the Public Health Service Act by Pub. L. 98–24, § 2(b)(16)(B), Apr. 26, 1983, 97 Stat. 182, and is classified to section 290ee–2 of Title 42, The Public Health and Welfare.

Section 1175, Pub. L. 92–255, title IV, § 408, Mar. 21, 1972, 86 Stat. 79; Pub. L. 93–282, title III, § 303(a), (b), May 14, 1974, 88 Stat. 137, 138; Pub. L. 94–237, § 4(c)(5)(A), (B), Mar. 19, 1976, 90 Stat. 244; Pub. L. 94–581, title I, § 111(c)(3), Oct. 21, 1976, 90 Stat. 2852; Pub. L. 97–35, title IX, § 973(d), Aug. 13, 1981, 95 Stat. 598, which related to confidentiality of patients' records, was redesignated section 527 of the Public Health Service Act by Pub. L. 98–24, § 2(b)(16)(B), Apr. 26, 1983, 97 Stat. 182, and is classified to section 290ee–3 of Title 42.

### § 1176. Repealed. Pub. L. 97–35, title IX, § 969(a), Aug. 13, 1981, 95 Stat. 595

Section, Pub. L. 92–255, title IV, § 409, Mar. 21, 1972, 86 Stat. 80; Pub. L. 94–237, §§ 7, 8(a), 9(a)(1), (b)(1), Mar. 19, 1976, 90 Stat. 245–247; Pub. L. 94–371, § 10(a)(1), (b)(1), July 26, 1976, 90 Stat. 1040; Pub. L. 95–83, title III,

§ 311(a)(3), Aug. 1, 1977, 91 Stat. 397; Pub. L. 95–461, §§ 2(a), 4, Oct. 14, 1978, 92 Stat. 1268, 1269; Pub. L. 96–79, title I, § 115(j)(2), Oct. 4, 1979, 93 Stat. 610; Pub. L. 96–181, § 6, Jan. 2, 1980, 93 Stat. 1311, provided for creation and funding through the fiscal year ending Sept. 30, 1981, of a program of formula grants to States to operate State plans for the establishment, conduct, and coordination of projects for the development of more effective drug abuse prevention functions in the States and for the evaluation of such programs.

### § 1177. Special project grants and contracts

#### (a) Scope of programs; priority

The Secretary[1] acting through the National Institute on Drug Abuse, may make grants to and enter into contracts with individuals and public and private nonprofit entities—

(1) to provide training seminars, educational programs, and technical assistance for the development, demonstration, and evaluation of drug abuse prevention, treatment, and rehabilitation programs; and

(2) to conduct demonstration and evaluation projects, with a high priority on prevention and early intervention projects and on identifying new and more effective drug abuse prevention, treatment, and rehabilitation programs.

In the implementation of his authority under this section, the Secretary shall accord a high priority to applications for grants or contracts for primary prevention programs. For purposes of the preceding sentence, primary prevention programs include programs designed to discourage persons from beginning drug abuse. To the extent that appropriations authorized under this section are used to fund treatment services, the Secretary shall not limit such funding to treatment for opiate abuse, but shall also provide support for treatment for non-opiate drug abuse including polydrug abuse. Furthermore, nothing shall prevent the use of funds provided under this section for programs and projects aimed at the prevention, treatment, and rehabilitation of alcohol abuse and alcoholism as well as drug abuse.

#### (b) Authorization of appropriations

There are authorized to be appropriated $25,000,000 for the fiscal year ending June 30, 1972; $65,000,000 for the fiscal year ending June 30, 1973; $100,000,000 for the fiscal year ending June 30, 1974; $160,000,000 for each of the fiscal years ending June 30, 1975 and June 30, 1976; $40,000,000 for the period July 1, 1976, through September 30, 1976; and $160,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978, to carry out this section. For the fiscal year ending September 30, 1979, there is authorized to be appropriated (1) $153,000,000 for grants and contracts under paragraphs (3) and (6) of subsection (a) of this section for drug abuse treatment programs, and (2) $24,000,000 for grants and contracts under such subsection for other programs and activities. For grants and contracts under paragraphs (3) and (6) of subsection (a) of this section for drug abuse treatment programs there is authorized to be appropriated $149,000,000 for the fiscal year ending September 30, 1980, and $155,000,000 for the fiscal year ending September 30, 1981; and for grants and contracts under such subsection for other programs and activities there is authorized to be appropriated $20,000,000 for the fiscal year ending September 30, 1980, and $30,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under the preceding sentence for the fiscal year ending September 30, 1980, at least 7 percent of the funds shall be obligated for grants and contracts for primary prevention and intervention programs designed to discourage individuals, particularly those in high risk populations, from abusing drugs; and of the funds appropriated under the preceding sentence for the next fiscal year, at least 10 percent of the funds shall be obligated for such grants and contracts. For carrying out the purposes of this section, there are authorized to be appropriated $15,000,000 for the fiscal year ending September 30, 1982. Of the funds appropriated under the preceding sentence, at least 25 per centum of the funds shall be obligated for grants and contracts for primary prevention and intervention programs designed to discourage individuals, particularly individuals in high risk populations, from abusing drugs.

#### (c) Coordination of applications for programs in a State; precedence restriction; project evaluation; application approval; criteria; proposed performance standards or research protocol

(1) In carrying out this section, the Secretary shall require coordination of all applications for programs in a State and shall not give precedence to public agencies over private agencies, institutions, and organizations, or to State agencies over local agencies.

(2) Each applicant within a State, upon filing its application with the Secretary for a grant or contract under this section, shall submit a copy of its application for review by the State agency (if any) responsible for the administration of drug abuse prevention activities. Such State agency shall be given not more than thirty days from the date of receipt of the application to submit to the Secretary, in writing, an evaluation of the project set forth in the application. Such evaluation shall include comments on the relationship of the project to other projects pending and approved and to any State comprehensive plan for treatment and prevention of drug abuse. The State shall furnish the applicant a copy of any such evaluation. A State if it so desires may, in writing, waive its rights under this paragraph.

(3) Approval of any application for a grant or contract under this section by the Secretary, including the earmarking of financial assistance for a program or project, may be granted only if the application substantially meets a set of criteria that—

(A) provide that the activities and services for which assistance under this section is sought will be substantially administered by or under the supervision of the applicant;

(B) provide for such methods of administration as are necessary for the proper and efficient operation of such programs or projects; and

[1] So in original. Probably should be followed by a comma.

(C) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant.

(4) Each applicant within a State, upon filing its application with the Secretary for a grant or contract to provide treatment or rehabilitation services shall provide a proposed performance standard or standards, to measure, or research protocol to determine, the effectiveness of such treatment or rehabilitation program or project.

**(d) Programs and projects aimed at underserved groups; encouragement and special consideration given to applications**

The Secretary shall encourage the submission of and give special consideration to applications under this section to programs and projects aimed at underserved populations such as racial and ethnic minorities, Native Americans (including Native Hawaiians and Native American Pacific Islanders), youth, the elderly, women, handicapped individuals, and families of drug abusers.

**(e) Payments; advances; reimbursement; installments**

Payment under grants or contracts under this section may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

**(f) Prevention and treatment services**

Projects and programs for which grants and contracts are made or entered into under this section shall, in the case of prevention and treatment services, seek to (1) be responsive to special requirements of handicapped individuals in receiving such services; (2) whenever possible, be community based, insure care of good quality in general community care facilities and under health insurance plans, and be integrated with, and provide for the active participation of, a wide range of public and nongovernmental agencies, organizations, institutions, and individuals; (3) where a substantial number of the individuals in the population served by the project or program are of limited English-speaking ability (A) utilize the services of outreach workers fluent in the language spoken by a predominant number of such individuals and develop a plan and make arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and (B) identify an individual who is fluent both in that language and English and whose responsibilities shall include providing guidance to the individuals of limited English-speaking ability and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences; and (4) where appropriate, utilize existing community resources (including community mental health centers).

**(g) Authorization by chief executive officer of State required; maximum amount and duration of grants**

(1) No grant may be made under this section to a State or to any entity within the government of a State unless the grant application has been duly authorized by the chief executive officer of such State.

(2) No grant or contract may be made under this section for a period in excess of five years.

(3)(A) The amount of any grant or contract under this section may not exceed 100 per centum of the cost of carrying out the grant or contract in the first fiscal year for which the grant or contract is made under this section, 80 per centum of such cost in the second fiscal year for which the grant or contract is made under this section, 70 per centum of such cost in the third fiscal year for which the grant or contract is made under this section, and 60 per centum of such cost in each of the fourth and fifth fiscal years for which the grant or contract is made under this section.

(B) For purposes of this paragraph, no grant or contract shall be considered to have been made under this section for a fiscal year ending before September 30, 1981.

(Pub. L. 92–255, title IV, § 410, Mar. 21, 1972, 86 Stat. 82; Pub. L. 94–237, §§ 10, 11, Mar. 19, 1976, 90 Stat. 247; Pub. L. 94–371, § 10(c)(1), July 26, 1976, 90 Stat. 1040; Pub. L. 95–461, §§ 2(b), 6(a), Oct. 14, 1978, 92 Stat. 1268, 1270; Pub. L. 96–181, § 7, Jan. 2, 1980, 93 Stat. 1312; Pub. L. 97–35, title IX, § 970(b)–(f), Aug. 13, 1981, 95 Stat. 596, 597; Pub. L. 98–24, § 5(a)(3), Apr. 26, 1983, 97 Stat. 183.)

AMENDMENTS

1983—Subsec. (d). Pub. L. 98–24 substituted ''Native Americans (including Native Hawaiians and Native American Pacific Islanders)'' for ''native Americans''.

1981—Subsec. (a). Pub. L. 97–35, § 970(b), substituted ''The Secretary acting through the National Institute on Drug Abuse, may make grants to and enter into contracts with individuals, and public and private nonprofit entities'' for ''The Secretary shall'' in introductory provision preceding par. (1), reduced the enumeration of authorized activities of the Secretary from six paragraphs to two paragraphs thereby eliminating provisions relating to the recruitment, training, and employment of participants in treatment programs, the establishment, conduct, and evaluation of drug abuse prevention, treatment, and rehabilitation programs, the development of methods to deal with drug abuse in particular areas, the improvement of drug maintenance techniques or programs, and the establishment, conduct, and evaluation of drug abuse prevention and treatment programs, and inserted provision that nothing shall prevent the use of funds provided under this section for programs and projects aimed at the prevention, treatment, and rehabilitation of alcohol abuse and alcoholism as well as drug abuse.

Subsec. (b). Pub. L. 97–35, § 970(c), inserted provisions relating to fiscal year ending Sept. 30, 1982.

Subsec. (c)(2). Pub. L. 97–35, § 970(d)(1), substituted ''responsible for the administration of drug abuse prevention activities'' for ''designated or established under section 1176 of this title'' and ''any State'' for ''the State'' and struck out reference to drug abuse under section 1176 of this title.

Subsec. (c)(3)(D). Pub. L. 97–35, § 970(d)(2), struck out subpar. (D) which had provided that approval of a grant or contract could be granted only if the application provided for reasonable assurances that Federal funds made available under this section would be used to supplement and increase the level of State, local, and other non-Federal funds that would in the absence of such Federal funds be made available for the programs described in this section and would not supplant State or local funds.

Subsec. (d). Pub. L. 97–35, § 970(e), inserted applicability to racial and ethnic minorities, handicapped, native Americans, and families of drug abusers.

Subsec. (g). Pub. L. 97–35, § 970(f), added subsec. (g).

1980—Subsec. (a)(1). Pub. L. 96–181, § 7(a)(1), substituted ''development, demonstration and evaluation of drug abuse'' for ''development of drug abuse''.

Subsec. (a)(5). Pub. L. 96–181, § 7(a)(2), substituted ''drug maintenance and detoxification techniques'' for ''drug maintenance techniques''.

Subsec. (a)(6). Pub. L. 96–181, § 7(a)(3), in provisions relating to evaluation of drug abuse prevention and treatment programs, inserted provision that such evaluation be with particular emphasis on replicating effective prevention and treatment programs.

Subsec. (b). Pub. L. 96–181, § 7(b), inserted authorization of appropriations for grants and contracts under pars. (3) and (6) of subsec. (a) and for other programs and activities for fiscal years ending Sept. 30, 1980, and Sept. 30, 1981, and required certain percentage of appropriated funds to be obligated for grants and contracts for primary prevention and intervention programs designed to discourage individuals from abusing drugs.

Subsec. (d). Pub. L. 96–181, § 7(c), inserted provisions for special consideration to applications for programs and projects for prevention and treatment of drug abuse and drug dependence by elderly.

Subsec. (f). Pub. L. 96–181, § 7(d), added subsec. (f).

1978—Subsec. (a). Pub. L. 95–461, § 6(a), inserted provision requiring Secretary to act through National Institute on Drug Abuse in making special project grants.

Subsec. (b). Pub. L. 95–461, § 2(b), inserted provisions authorizing appropriations for fiscal year ending Sept. 30, 1979.

1976—Subsec. (a). Pub. L. 94–237, § 10(a), inserted provisions which authorized Secretary to give a high priority to applications for grants and contracts for primary prevention programs, and set forth programs included within primary prevention programs and scope of Secretary's funding authority.

Subsec. (b). Pub. L. 94–237, § 11, substituted ''$160,000,000 for each of the fiscal years ending June 30, 1975 and June 30, 1976; $40,000,000 for the period July 1, 1976, through September 30, 1976; and $160,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978,'' for ''and $160,000,000 for the fiscal year ending June 30, 1975,''.

Subsec. (c)(4). Pub. L. 94–237, § 10(b), added par. (4).

Subsecs. (d), (e). Pub. L. 94–371 added subsec. (d) and redesignated former subsec. (d) as (e).

EFFECTIVE DATE OF 1976 AMENDMENT

Section 10(c)(2) of Pub. L. 94–371 provided that: ''The amendment made by paragraph (1) [amending this section] shall apply with respect to applications submitted for grants or contracts under section 410 of the Drug Abuse Office and Treatment Act of 1972 [this section] after June 30, 1976.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1178 of this title.

## § 1178. Records and audit

### (a) Assistance records; contents

Each recipient of assistance under section 1177 of this title pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the project or undertaking in connection with which such grant or contract is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

### (b) Access to pertinent information for audit and examination

The Secretary and Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to such grants or contracts.

(Pub. L. 92–255, title IV, § 411, Mar. 21, 1972, 86 Stat. 83; Pub. L. 97–35, title IX, § 971, Aug. 13, 1981, 95 Stat. 597.)

AMENDMENTS

1981—Subsec. (a). Pub. L. 97–35 struck out reference to section 1176 of this title.

## § 1179. National Drug Abuse Training Center

### (a) Establishment; functions; general policies; transfer of supervision

The Director shall establish a National Drug Abuse Training Center (hereinafter in this section referred to as the ''Center'') to develop, conduct, and support a full range of training programs relating to drug abuse prevention functions. The Director shall consult with the National Advisory Council for Drug Abuse Prevention regarding the general policies of the Center. The Director may supervise the operation of the Center initially, but shall transfer the supervision of the operation of the Center to the National Institute on Drug Abuse not later than December 31, 1974.

### (b) Activities and material

The Center shall conduct or arrange for training programs, seminars, meetings, conferences, and other related activities, including the furnishing of training and educational materials for use by others.

### (c) Persons eligible for services and facilities

The services and facilities of the Center shall, in accordance with regulations prescribed by the Director, be available to (1) Federal, State, and local governmental officials, and their respective staffs, (2) medical and paramedical personnel, and educators, and (3) other persons, including drug dependent persons, requiring training or education in drug abuse prevention.

### (d) Authorization of appropriations; fiscal year availability

(1) For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for the fiscal year ending June 30, 1972, $3,000,000 for the fiscal year ending June 30, 1973, $5,000,000 for the fiscal year ending June 30, 1974, and $6,000,000 for the fiscal year ending June 30, 1975.

(2) Sums appropriated under this subsection shall remain available for obligation or expenditure in the fiscal year for which appropriated and in the fiscal year next following.

(Pub. L. 92–255, title IV, § 412, Mar. 21, 1972, 86 Stat. 84.)

NATIONAL ADVISORY COUNCIL FOR DRUG ABUSE PREVENTION

Section 1151 of this title, which established the National Advisory Council for Drug Abuse Prevention, was repealed by Pub. L. 92–255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

## § 1180. Transferred

Section, Pub. L. 92–255, title IV, § 413, Mar. 21, 1972, 86 Stat. 84; Pub. L. 96–181, § 8(a), (b)(1), Jan. 2, 1980, 93 Stat.

1313, 1314; Pub. L. 97–35, title IX, § 973(e), Aug. 13, 1981, 95 Stat. 598, which related to drug abuse among government and other employees, was redesignated section 525 of the Public Health Service Act by Pub. L. 98–24, § 2(b)(16)(A), Apr. 26, 1983, 97 Stat. 182, and is classified to section 290ee–1 of Title 42, The Public Health and Welfare.

### § 1181. Contract authority

The authority of the Secretary to enter into contracts under this subchapter and subchapter V of this chapter shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

(Pub. L. 92–255, title IV, § 414, as added Pub. L. 96–181, § 9(a), Jan. 2, 1980, 93 Stat. 1314.)

REFERENCES IN TEXT

Subchapter V of this chapter, referred to in text, consisted of sections 501 to 504 of title V of Pub. L. 92–255, Mar. 21, 1972, 86 Stat. 85, which were classified to sections 1191 to 1194 of this title, respectively. Sections 501 to 503 were made part of the Public Health Service Act by Pub. L. 98–24, § 2(b)(4), (11), (15), Apr. 26, 1983, 97 Stat. 177, 180, 181, and were transferred to sections 290aa–2, 290ee, and 290cc, respectively, of Title 42, The Public Health and Welfare. Section 504 was repealed by Pub. L. 98–24, § 2(c)(2).

## SUBCHAPTER V—NATIONAL INSTITUTE ON DRUG ABUSE

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 1181 of this title.

### §§ 1191 to 1193. Transferred

Section 1191, Pub. L. 92–255, title V, § 501, Mar. 21, 1972, 86 Stat. 85; Pub. L. 93–282, title II, § 204, May 14, 1974, 88 Stat. 136; Pub. L. 94–237, § 12(a), Mar. 19, 1976, 90 Stat. 247; Pub. L. 96–181, § 10, Jan. 2, 1980, 93 Stat. 1314; Pub. L. 97–35, title IX, § 973(f), Aug. 13, 1981, 95 Stat. 598, which established the National Institute on Drug Abuse, was redesignated section 503(a)–(d) of the Public Health Service Act by Pub. L. 98–24, § 2(b)(4), Apr. 26, 1983, 97 Stat. 177, and is classified to section 290aa–2(a)–(d) of Title 42, The Public Health and Welfare.

Section 1192, Pub. L. 92–255, title V, § 502, as added Pub. L. 94–237, § 12(b)(1), Mar. 19, 1976, 90 Stat. 247; amended Pub. L. 95–461, § 5, Oct. 14, 1978, 92 Stat. 1269; Pub. L. 96–181, § 11, Jan. 2, 1980, 93 Stat. 1315, which related to the coordination, information, assistance, and assignment activities and services, was redesignated section 524 of the Public Health Service Act by Pub. L. 98–24, § 2(b)(15), Apr. 26, 1983, 97 Stat. 181, and is classified to section 290ee of Title 42.

Section 1193, Pub. L. 92–255, title V, § 503, as added Pub. L. 94–237, § 13(a), Mar. 19, 1976, 90 Stat. 248; amended Pub. L. 95–461, § 2(c), Oct. 14, 1978, 92 Stat. 1268; Pub. L. 96–181, § 12, Jan. 2, 1980, 93 Stat. 1315; Pub. L. 97–35, title IX, § 972(a), (b), Aug. 13, 1981, 95 Stat. 597, which related to research and development functions, was redesignated section 515 of the Public Health Service Act by Pub. L. 98–24, § 2(b)(11), Apr. 26, 1983, 97 Stat. 180, and is classified to section 290cc of Title 42.

PRIOR PROVISIONS

A prior section 502 of Pub. L. 92–255, Mar. 21, 1972, 86 Stat. 85, amended section 217 of the Public Health Service Act by adding subsec. (e) [section 218(e) of Title 42, The Public Health and Welfare], and amended section 266 of the Community Mental Health Centers Act [former section 2688t of Title 42].

### § 1194. Repealed. Pub. L. 98–24, § 2(c)(2), Apr. 26, 1983, 97 Stat. 182

Section, Pub. L. 92–255, title V, § 504, as added Pub. L. 95–461, § 6(b)(1), Oct. 14, 1978, 92 Stat. 1270, related to review by the Secretary of programs and activities. See section 290aa–5 of Title 42, The Public Health and Welfare.

## CHAPTER 17—NATIONAL DRUG ENFORCEMENT POLICY

### §§ 1201 to 1204. Repealed. Pub. L. 100–690, title I, § 1007(a)(3), Nov. 18, 1988, 102 Stat. 4187

Section 1201, Pub. L. 98–473, title II, § 1302, Oct. 12, 1984, 98 Stat. 2168, set forth Congressional findings and declaration of purpose relating to illegal flow of narcotics into United States.

Section 1202, Pub. L. 98–473, title II, § 1303, Oct. 12, 1984, 98 Stat. 2168, established National Drug Enforcement Policy Board.

Section 1203, Pub. L. 98–473, title II, § 1304, Oct. 12, 1984, 98 Stat. 2169, delineated responsibilities and functions of National Drug Enforcement Policy Board.

Section 1204, Pub. L. 98–473, title II, § 1305, Oct. 12, 1984, 98 Stat. 2170, related to reports to Congress.

EFFECTIVE DATE OF REPEAL

Section 1007(a)(3) of Pub. L. 100–690 provided that the repeal of this chapter is effective on 30th day after first Director of National Drug Control Policy is confirmed by the Senate. See section 1501 et seq. of this title.

SHORT TITLE

Pub. L. 98–473, title II, § 1301, Oct. 12, 1984, 98 Stat. 2168, which provided that chapter XIII (§§ 1301 to 1307) of title II of Pub. L. 98–473 was to be cited as the National Narcotics Act of 1984, was repealed by Pub. L. 100–690, title I, § 1007(a)(3), Nov. 18, 1988, 102 Stat. 4187.

EXECUTIVE ORDER NO. 12590

Ex. Ord. No. 12590, Mar. 26, 1987, 52 F.R. 10021, provided for the establishment of a National Drug Policy Board, designated its membership and functions, and authorized coordinating groups.

## CHAPTER 18—PRESIDENT'S MEDIA COMMISSION ON ALCOHOL AND DRUG ABUSE PREVENTION

Sec.
1301. Establishment.
1302. Duties of Commission.
1303. Membership.
(a) Number and appointment.
(b) Terms.
(c) Basic pay and expenses.
1304. Meetings.
(a) In general.
(b) Moderator.
(c) Quorum and procedure.
(d) Voting.
1305. Director and staff; experts and consultants.
(a) Director and staff.
(b) Experts and consultants.
(c) Staff of Federal agencies.
1306. Powers of Commission.
(a) Hearings and sessions.
(b) Obtaining official data.
(c) Gifts.
(d) Mails.
(e) Administrative support services.
1307. Report.
1308. Termination.

### § 1301. Establishment

There is established a commission to be known as the President's Media Commission on

Alcohol and Drug Abuse Prevention (hereinafter in this chapter referred to as the ''Commission'').

(Pub. L. 99–570, title VIII, § 8002, Oct. 27, 1986, 100 Stat. 3207–161.)

SHORT TITLE

Section 8001 of title VIII of Pub. L. 99–570 provided that: ''This title [enacting this chapter] may be cited as the 'President's Media Commission on Alcohol and Drug Abuse Prevention Act'.''

### § 1302. Duties of Commission

The Commission shall—

(1) examine public education programs in effect on October 27, 1986, which are—

(A) implemented through various segments of mass media; and

(B) intended to prevent alcohol and drug abuse;

(2) act as an administrative and coordinating body for the voluntary donation of resources from—

(A) television, radio, motion picture, cable communications, and print media;

(B) the recording industry;

(C) the advertising industry;

(D) the business sector of the United States; and

(E) professional sports organizations and associations;

to assist the implementation of new programs and national strategies for dissemination of information intended to prevent alcohol and drug abuse;

(3) encourage media outlets throughout the country to provide information aimed at preventing alcohol and drug abuse, including public service announcements, documentary films, and advertisements; and

(4) evaluate the effectiveness and assist in the update of programs and national strategies formulated with the assistance of the Commission.

(Pub. L. 99–570, title VIII, § 8003, Oct. 27, 1986, 100 Stat. 3207–161.)

### § 1303. Membership

#### (a) Number and appointment

The Commission shall be composed of 12 members appointed by the President within 30 days after October 27, 1986, and should include representatives of—

(1) advertising agencies;

(2) motion picture, television, radio, cable communications, and print media;

(3) the recording industry;

(4) other segments of the business sector of the United States;

(5) experts in the prevention of alcohol and drug abuse;

(6) professional sports organizations and associations; and

(7) other Federal agencies, as designated by the President, including the Director of the Agency for Substance Abuse Prevention of the Department of Health and Human Services.

#### (b) Terms

(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of 3 years.

(2) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term.

(3) A member may serve after the expiration of his term until his successor has taken office.

#### (c) Basic pay and expenses

(1) Except as provided in paragraph (2), members of the Commission shall serve without pay.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members shall be allowed travel expenses, including a per diem allowance in lieu of subsistence, in the same manner as persons serving intermittently in the Government service are allowed travel expenses under section 5703 of title 5.

(Pub. L. 99–570, title VIII, § 8004, Oct. 27, 1986, 100 Stat. 3207–162.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1304 of this title.

### § 1304. Meetings

#### (a) In general

(1) The Commission shall meet at the call of the Moderator.

(2) The Moderator shall convene the 1st meeting of the Commission within 30 days after the date of the completion of appointments under section 1303(a) of this title.

#### (b) Moderator

One member of the Commission shall be designated by the President to serve as Moderator of the Commission.

#### (c) Quorum and procedure

The Commission shall adopt rules regarding quorum requirements and meeting procedures as the Commission deems appropriate at the 1st meeting of the Commission.

#### (d) Voting

Decisions and official acts of the Commission shall be according to the vote of a majority of members at a properly called meeting.

(Pub. L. 99–570, title VIII, § 8005, Oct. 27, 1986, 100 Stat. 3207–162.)

### § 1305. Director and staff; experts and consultants

#### (a) Director and staff

(1) Subject to paragraph (2), the Moderator, with the approval of the Commission, may employ and set the rate of pay for a Director and such staff as the Moderator deems necessary.

(2) Rates of pay set under paragraph (1) shall be less than the rate of basic pay payable under section 5316 of title 5.

#### (b) Experts and consultants

The Moderator, with the approval of the Commission, may procure temporary and intermittent services under section 3109(b) of title 5.

#### (c) Staff of Federal agencies

Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such

agency to the Commission to assist the Commission in carrying out its duties under this chapter.

(Pub. L. 99–570, title VIII, § 8006, Oct. 27, 1986, 100 Stat. 3207–163.)

### § 1306. Powers of Commission

**(a) Hearings and sessions**

The Commission may, for the purpose of carrying out this chapter, hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate.

**(b) Obtaining official data**

Upon the request of the Moderator of the Commission, the Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this chapter.

**(c) Gifts**

The Commission may accept, use, and dispose of gifts or donations of services or property.

**(d) Mails**

The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

**(e) Administrative support services**

The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

(Pub. L. 99–570, title VIII, § 8007, Oct. 27, 1986, 100 Stat. 3207–163.)

### § 1307. Report

The Commission shall transmit to the President and to each House of Congress a report not later than July 31 of each year which contains a detailed statement of the activities of the Commission during the preceding year, including a summary of the number of public service announcements produced by the Commission and published or broadcast.

(Pub. L. 99–570, title VIII, § 8008, Oct. 27, 1986, 100 Stat. 3207–163.)

### § 1308. Termination

The Commission shall terminate on a date which is three years after the date on which members of the Commission are first appointed, unless the President, by Executive order, extends the authority of the Commission.

(Pub. L. 99–570, title VIII, § 8009, Oct. 27, 1986, 100 Stat. 3207–163.)

## CHAPTER 19—PESTICIDE MONITORING IMPROVEMENTS

Sec.
1401. Pesticide monitoring and enforcement information.
(a) Data management systems.
(b) Information.
(c) Volume data.
(d) Compilation.
1402. Foreign pesticide information.
(a) Cooperative agreements.
(b) Information activities.
(c) Coordination with other agencies.
(d) Report.
1403. Pesticide analytical methods.

### § 1401. Pesticide monitoring and enforcement information

**(a) Data management systems**

(1) Not later than 480 days after August 23, 1988, the Secretary of Health and Human Services shall place in effect computerized data management systems for the Food and Drug Administration under which the Administration will—

(A) record, summarize, and evaluate the results of its program for monitoring food products for pesticide residues,

(B) identify gaps in its pesticide monitoring program in the monitoring of (i) pesticides, (ii) food products, and (iii) food from specific countries and from domestic sources,

(C) detect trends in the presence of pesticide residues in food products and identify public health problems emerging from the occurrence of pesticide residues in food products,

(D) focus its testing resources for monitoring pesticide residues in food on detecting those residues which pose a public health concern,

(E) prepare summaries of the information listed in subsection (b) of this section, and

(F) provide information to assist the Environmental Protection Agency in carrying out its responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(2) As soon as practicable, the Secretary of Health and Human Services shall develop a means to enable the computerized data management systems placed into effect under paragraph (1) to make the summary described in subsection (c) of this section.

(3)(A) Paragraph (1) does not limit the authority of the Food and Drug Administration to—

(i) use the computerized data management systems placed in effect under paragraph (1), or

(ii) develop additional data management systems,

to facilitate the regulation of any substance or product covered under the requirements of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(B) In placing into effect the computerized data management systems under paragraph (1) and in carrying out paragraph (2), the Secretary shall comply with applicable regulations governing computer system design and procurement.

**(b) Information**

The Food and Drug Administration shall use the computerized data management systems placed into effect under subsection (a)(1) of this section to prepare a summary of—

(1) information on—

(A) the types of imported and domestically produced food products analyzed for compliance with the requirements of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301

et seq.] regarding the presence of pesticide residues,

(B) the number of samples of each such food product analyzed for such compliance by country of origin,

(C) the pesticide residues which may be detected using the testing methods employed,

(D) the pesticide residues in such food detected and the levels detected,

(E) the compliance status of each sample of such food tested and the violation rate for each country-product combination, and

(F) the action taken with respect to each sample of such food found to be in violation of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and its ultimate disposition, and

(2) information on—

(A) the country of origin of each imported food product referred to in paragraph (1)(A), and

(B) the United States district of entry for each such imported food product.

**(c) Volume data**

The Food and Drug Administration shall use the computerized data management systems placed into effect under subsection (a)(1) of this section to summarize the volume of each type of food product subject to the requirements of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] which is imported into the United States and which has an entry value which exceeds an amount established by the Secretary of Health and Human Services. The summary shall be made by country of origin and district of entry. Information with respect to volumes of food products to be included in the summary shall, to the extent feasible, be obtained from data bases of other Federal agencies.

**(d) Compilation**

Not later than 90 days after the expiration of 1 year after the data management systems are placed into effect under subsection (a) of this section and annually thereafter, the Secretary of Health and Human Services shall compile a summary of the information described in subsection (b) of this section with respect to the previous year. When the Food and Drug Administration is able to make summaries under subsection (c) of this section, the Secretary shall include in the compilation under the preceding sentence a compilation of the information described in subsection (c) of this section. Compilations under this subsection shall be made available to Federal and State agencies and other interested persons.

(Pub. L. 100–418, title IV, § 4702, Aug. 23, 1988, 102 Stat. 1412.)

REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (a)(1)(F), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a) to (c), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

SHORT TITLE

Section 4701 of Pub. L. 100–418 provided that: ''This subtitle [subtitle G (§§ 4701–4704) of title IV of Pub. L. 100–418, enacting this chapter] may be cited as the 'Pesticide Monitoring Improvements Act of 1988'.''

IMPORTED MEAT, POULTRY PRODUCTS, EGGS, AND EGG PRODUCTS

Section 4506 of Pub. L. 100–418 provided that:

''(a) REPORT.—Not later than 90 days after the date of the enactment of this Act [Aug. 23, 1988], the Secretary of Agriculture shall submit a report to Congress—

''(1) specifying the planned distribution, in fiscal years 1988 and 1989, of the resources of the Department of Agriculture available for sampling imported covered products to ensure compliance with the requirements of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.) that govern the level of residues of pesticides, drugs, and other products permitted in or on such products;

''(2) describing current methods used by the Secretary to enforce the requirements of such Acts with respect to the level of residues of pesticides, drugs, and other products permitted in or on such products;

''(3) responding to the audit report of the Inspector General of the Department of Agriculture, Number 38002—2—hy, dated January 14, 1987;

''(4) providing a summary with respect to the importation of covered products during fiscal years 1987 and 1988 that specifies—

''(A) the number of samples of each such product taken during each such fiscal year in carrying out the requirements described in paragraph (1); and

''(B) for each violation of such requirements during each such fiscal year—

''(i) the covered products with respect to which such violation occurred;

''(ii) the residue in or on such product in violation of such requirements;

''(iii) the country exporting such product;

''(iv) the actions taken in response to such violation and the reasons for such actions; and

''(v) the level of testing conducted by the countries exporting such products;

''(5) describing any research conducted by the Secretary to develop improved methods to detect residues subject to such requirements in or on covered products; and

''(6) providing any recommendations the Secretary considers appropriate for legislation to add or modify penalties for violations of laws, regulations, and other enforcement requirements governing the level of residues that are permitted in or on imported covered products.

''(b) REVISION.—Not later than November 15, 1989, the Secretary of Agriculture shall revise, as necessary, the report prepared under subsection (a) and submit the revision to Congress.

''(c) DEFINITION.—As used in this section, the term 'covered products' means meat, poultry products, eggs, and egg products.''

## § 1402. Foreign pesticide information

**(a) Cooperative agreements**

The Secretary of Health and Human Services shall enter into cooperative agreements with the governments of the countries which are the major sources of food imports into the United States subject to pesticide residue monitoring by the Food and Drug Administration for the

purpose of improving the ability of the Food and Drug Administration to assure compliance with the pesticide tolerance requirements of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] with regard to imported food.

**(b) Information activities**

(1) The cooperative agreements entered into under subsection (a) of this section with governments of foreign countries shall specify the action to be taken by the parties to the agreements to accomplish the purpose described in subsection (a) of this section, including the means by which the governments of the foreign countries will provide to the Secretary of Health and Human Services current information identifying each of the pesticides used in the production, transportation, and storage of food products imported from production regions of such countries into the United States.

(2) In the case of a foreign country with which the Secretary is unable to enter into an agreement under subsection (a) of this section or for which the information provided under paragraph (1) is insufficient to assure an effective pesticide monitoring program, the Secretary shall, to the extent practicable, obtain the information described in paragraph (1) with respect to such country from other Federal or international agencies or private sources.

(3) The Secretary of Health and Human Services shall assure that appropriate offices of the Food and Drug Administration which are engaged in the monitoring of imported food for pesticide residues receive the information obtained under paragraph (1) or (2).

(4) The Secretary of Health and Human Services shall make available any information obtained under paragraph (1) or (2) to State agencies engaged in the monitoring of imported food for pesticide residues other than information obtained from private sources the disclosure of which to such agencies is restricted.

**(c) Coordination with other agencies**

The Secretary of Health and Human Services shall—

(1) notify in writing the Department of Agriculture, the Environmental Protection Agency, and the Department of State at the initiation of negotiations with a foreign country to develop a cooperative agreement under subsection (a) of this section; and

(2) coordinate the activities of the Department of Health and Human Services with the activities of those departments and agencies, as appropriate, during the course of such negotiations.

**(d) Report**

Not later than one year after August 23, 1988, the Secretary of Health and Human Services shall report to the Committee on Agriculture, Nutrition, and Forestry and the Committee on Labor and Human Resources of the Senate and the House of Representatives on the activities undertaken by the Secretary to implement this section. The report shall be made available to appropriate Federal and State agencies and to interested persons.

(Pub. L. 100–418, title IV, § 4703, Aug. 23, 1988, 102 Stat. 1413.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

### § 1403. Pesticide analytical methods

The Secretary of Health and Human Services shall, in consultation with the Administrator of the Environmental Protection Agency—

(1) develop a detailed long-range plan and timetable for research that is necessary for the development of and validation of—

(A) new and improved analytical methods capable of detecting at one time the presence of multiple pesticide residues in food, and

(B) rapid pesticide analytical methods, and

(2) conduct a review to determine whether the use of rapid pesticide analytical methods by the Secretary would enable the Secretary to improve the cost-effectiveness of monitoring and enforcement activities under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including increasing the number of pesticide residues which can be detected and the number of tests for pesticide residues which can be conducted in a cost-effective manner.

The Secretary shall report the plan developed under paragraph (1), the resources necessary to carry out the research described in such paragraph, recommendations for the implementation of such research, and the result of the review conducted under paragraph (2) not later than the expiration of 240 days after August 23, 1988, to the Committee on Agriculture, Nutrition, and Forestry and the Committee on Labor and Human Resources of the Senate and the House of Representatives.

(Pub. L. 100–418, title IV, § 4704, Aug. 23, 1988, 102 Stat. 1414.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

## CHAPTER 20—NATIONAL DRUG CONTROL PROGRAM

Sec.
1501. Establishment of Office of National Drug Control Policy.
(a) Establishment of Office.
(b) Director and Deputy Directors.
(c) Bureau of State and Local Affairs.
(d) Access by Congress.
1502. Appointment and duties of Director, Deputy Directors, and Associate Director.
(a) Appointment.
(b) Responsibilities.
(c) National Drug Control Program budget.
(d) Powers of Director.
(e) Personnel detailed to the Office.
(f) Funds control notices.
(f) Prohibition on political campaigning.

Sec.
1502a. Transferred.
1503. Coordination with executive branch departments and agencies.
(a) Access to information.
(b) Certification of policy changes by Director.
(c) General Services Administration.
1504. Development and submission of National Drug Control Strategy.
(a) Development and submission of National Drug Control Strategy.
(b) Goals, objectives, and priorities.
(c) High intensity drug trafficking areas.
(d) Lead agencies.
1505. Counter-Drug Technology Assessment Center.
(a) Establishment.
(b) Chief Scientist.
(c) Additional responsibilities of Director.
(d) Counter-drug budget submission.
(e) Personnel.
(f) Assistance and support to Office of National Drug Control Policy.
1506. Termination of Office of National Drug Control Policy.
1507. Definitions.
1508. Authorization of appropriations.
1509. Establishment of Special Forfeiture Fund.
(a) In general.
(b) Deposits.
(c) Super surplus.
(d) Investment of Fund.
(e) President's budget.
(f) Funds provided supplemental.
(g) Annual report.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in title 22 section 2291.

## § 1501. Establishment of Office of National Drug Control Policy

### (a) Establishment of Office

There is established in the Executive Office of the President the ''Office of National Drug Control Policy''.

### (b) Director and Deputy Directors

(1) There shall be at the head of the Office of National Drug Control Policy a Director of National Drug Control Policy.

(2) There shall be in the Office of National Drug Control Policy a Deputy Director for Demand Reduction and a Deputy Director for Supply Reduction.

(3) The Deputy Director for Demand Reduction and the Deputy Director for Supply Reduction shall assist the Director in carrying out the responsibilities of the Director under this Act.

### (c) Bureau of State and Local Affairs

(1) There is established in the Office of National Drug Control Policy a Bureau of State and Local Affairs.

(2) There shall be at the head of such bureau an Associate Director for National Drug Control Policy.

### (d) Access by Congress

The location of the Office of National Drug Control Policy in the Executive Office of the President shall not be construed as affecting access by the Congress or committees of either House to—

(1) information, documents, and studies in the possession of, or conducted by or at the direction of the Director; or

(2) personnel of the Office of National Drug Control Policy.

(Pub. L. 100–690, title I, § 1002, Nov. 18, 1988, 102 Stat. 4181.)

REPEAL OF SECTION

*For repeal of section on Sept. 30, 1997, see section 1506 of this title.*

REFERENCES IN TEXT

This Act, referred to in subsec. (b)(3), is Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4181, known as the Anti-Drug Abuse Act of 1988. For complete classification of this Act to the Code, see Short Title note set out under this section and Tables.

EFFECTIVE DATE

Section 1012 of Pub. L. 100–690 provided that: ''This subtitle [subtitle A (§§ 1001–1012) of title I of Pub. L. 100–690, see Short Title note below] shall be effective January 21, 1989.''

SHORT TITLE

Section 1 of Pub. L. 100–690 provided that: ''This Act [see Tables for classification] may be cited as the 'Anti-Drug Abuse Act of 1988'.''

Section 1001 of Pub. L. 100–690 provided that: ''This subtitle [subtitle A (§§ 1001–1012) of title I of Pub. L. 100–690, enacting sections 1501 to 1508 of this title, amending section 1115 of this title, sections 5312, 5314, and 5315 of Title 5, Government Organization and Employees, section 1105 of Title 31, Money and Finance, and section 402 of Title 50, War and National Defense, repealing sections 1103, 1111 to 1114, 1116, and 1201 to 1204 of this title, enacting provisions set out as notes under sections 1201 and 1501 of this title, and repealing provisions set out as notes under section 1201 of this title] may be cited as the 'National Narcotics Leadership Act of 1988'.''

TERMINATION OF NATIONAL DRUG ENFORCEMENT POLICY BOARD; TRANSFER OF RECORDS AND PROPERTY

Section 1007(a)(1), (2) of Pub. L. 100–690 provided that: ''(1) The National Drug Enforcement Policy Board is terminated effective on the 30th day after the first Director is confirmed by the Senate. Upon such termination, all records and property of the National Drug Enforcement Policy Board shall be transferred to the Director. The Director of the Office of Management and Budget shall take such actions as are necessary to facilitate such transfer.

''(2) All strategies, implementation plans, memoranda of understanding, and directives that have been issued or made by the National Drug Policy Board before the effective date of this subtitle [Jan. 21, 1989] shall continue in effect until modified, terminated, superseded, set aside, or revoked by the President or the Director.''

EXPENDITURE OF FUNDS FOR ACTIVITIES OF NATIONAL NARCOTICS BORDER INTERDICTION SYSTEM

Section 1007(b) of Pub. L. 100–690 provided that: ''Notwithstanding any other provision of law, no funds may be expended after 30 days after the date on which the first Director is confirmed by the Senate for any activities or operations of the entity otherwise known as the National Narcotics Border Interdiction System.''

TERMINATION OF WHITE HOUSE OFFICE OF DRUG ABUSE POLICY

Section 1007(c)(2) of Pub. L. 100–690 provided that: ''The White House Office of Drug Abuse Policy shall terminate on the 30th day after the date on which the first Director is confirmed by the Senate.''

EXECUTIVE ORDER NO. 12696

Ex. Ord. No. 12696, Nov. 13, 1989, 54 F.R. 47507, as amended by Ex. Ord. No. 12756, Mar. 18, 1991, 56 F.R.

11903, which established the President's Drug Advisory Council, was revoked by Ex. Ord. No. 12869, § 4(d), Sept. 30, 1993, 58 F.R. 51751, set out as a note under section 14 of the Federal Advisory Committee Act in the Appendix to Title 5, Government Organization and Employees.

EX. ORD. NO. 12911. SEAL FOR OFFICE OF NATIONAL DRUG CONTROL POLICY

Ex. Ord. No. 12911, Apr. 25, 1994, 59 F.R. 21121 [22121], provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. There is approved for the Office of National Drug Control Policy in the Executive Office of the President an official seal described as follows:

On a blue disc the Arms of the United States proper above a curved gold scroll inscribed ''OFFICE OF NATIONAL DRUG CONTROL POLICY'' in blue letters, all within a white border edged in gold and inscribed ''EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES'' in blue letters.

This design is appropriate for the Office of National Drug Control Policy. The dark blue in this seal is suggested by the Seal of the President and denotes the direct organizational link of the Office of National Drug Control Policy with the Presidential office. The Arms of the United States refer to the entire Nation and represent the involvement in drug control policies that are necessary to assist the President in his role as Chief Executive of the United States.

SEC. 2. The seal shall be of the design that is attached hereto and made a part of this order.

WILLIAM J. CLINTON.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 42 section 285*o*–4.

## § 1502. Appointment and duties of Director, Deputy Directors, and Associate Director

### (a) Appointment

(1) The Director, the Deputy Director for Demand Reduction, the Deputy Director for Supply Reduction, and the Associate Director for National Drug Control Policy shall each be appointed by the President, by and with the advice and consent of the Senate.

(2) The Director, the Deputy Director for Demand Reduction, the Deputy Director for Supply Reduction, and the Associate Director for National Drug Control Policy shall each serve at the pleasure of the President. No person shall serve as Director, a Deputy Director, or Associate Director while serving in any other position in the Federal Government.

(3), (4) Omitted

### (b) Responsibilities

The Director shall—

(1) establish policies, objectives, and priorities for the National Drug Control Program;

(2) annually promulgate the National Drug Control Strategy in accordance with section 1504 of this title;

(3) coordinate and oversee the implementation by National Drug Control Program agencies of the policies, objectives, and priorities established under paragraph (1) and the fulfillment of the responsibilities of such agencies under the National Drug Control Strategy;

(4) make such recommendations to the President as the Director determines are appropriate regarding—

(A) changes in the organization, management, and budgets of Federal departments and agencies engaged in drug enforcement; and

(B) the allocation of personnel to and within such departments and agencies;

to implement the policies, priorities, and objectives established under paragraph (1) and the National Drug Control Strategy;

(5) consult with and assist State and local governments with respect to their relations with the National Drug Control Program agencies;

(6) appear before duly constituted committees and subcommittees of the House of Representatives and of the Senate to represent the drug policies of the executive branch;

(7) notify any National Drug Control Program agency if its policies are not in compliance with the responsibilities of such agency under the National Drug Control Strategy and transmit a copy of each such notification to the President; and

(8) provide, by July 1 of each year, budget recommendations to the heads of departments and agencies with responsibilities under the National Drug Control Program, which recommendations shall apply to the second following fiscal year and address funding priorities developed in the annual National Drug Control Strategy.

### (c) National Drug Control Program budget

(1) The Director shall develop for each fiscal year, with the advice of the program managers of departments and agencies with responsibilities under the National Drug Control Program, a consolidated National Drug Control Program budget proposal to implement the National Drug Control Strategy, and shall transmit such budget proposal to the President and to the Congress.

(2) Each Federal Government program manager, agency head, and department head with responsibilities under the National Drug Control Strategy shall transmit the drug control budget request of the program, agency, or department to the Director at the same time as such request is submitted to their superiors (and before submission to the Office of Management and Budget) in the preparation of the budget of the President submitted to the Congress under section 1105(a) of title 31.

(3) The Director shall—

(A) review each drug control budget request transmitted to the Director under paragraph (2);

(B) certify in writing as to the adequacy of such request in whole or in part to implement the objectives of the National Drug Control Strategy for the year for which the request is submitted and, with respect to a request that is not certified as adequate to implement the objectives of the National Drug Control Strategy, include in the certification an initiative or funding level that would make the request adequate; and

(C) notify the program manager, agency head, or department head, as applicable, regarding the Director's certification under subparagraph (B).

(4) The Director shall maintain records regarding certifications under paragraph (3)(B).

(5) The Director shall request the head of a department or agency to include in the department's or agency's budget submission to the Office of Management and Budget funding requests for specific initiatives that are consistent with the President's priorities for the National Drug Control Strategy and certifications made pursuant to paragraph (3), and the head of the department or agency shall comply with such a request.

(6)(A) No National Drug Control Program agency shall submit to the Congress a reprogramming or transfer request with respect to any amount of appropriated funds greater than $5,000,000 which is included in the National Drug Control Program budget unless such request has been approved by the Director.

(B) The head of any National Drug Control Program agency may appeal to the President any disapproval by the Director of a reprogramming or transfer request.

(7) The Director shall report to the Congress on a quarterly basis regarding the need for any reprogramming or transfer of appropriated funds for National Drug Control Program activities.

(8) The head of each National Drug Control Program agency shall ensure timely development and submission to the Director of drug control budget requests transmitted pursuant to subsection (c)(2) of this section, in such format as may be designated by the Director with the concurrence of the Director of the Office of Management and Budget.

**(d) Powers of Director**

In carrying out the responsibilities established under subsection (b) of this section, the Director may—

(1) select, appoint, employ, and fix compensation of up to 75 and such additional officers and employees as may be necessary to carry out the functions of the Office of National Drug Control Policy under this title;[1]

(2) request the head of a department or agency or program to place department, agency, or program personnel who are engaged in drug control activities on temporary detail to another department or agency in order to implement the National Drug Control Strategy, and the head of the department or agency shall comply with such a request;

(3) use for administrative purposes, on a reimbursable basis, the available services, equipment, personnel, and facilities of Federal, State, and local agencies;

(4) procure the services of experts and consultants in accordance with section 3109 of title 5 relating to appointments in the Federal Service, at rates of compensation for individuals not to exceed the daily equivalent of the rate of pay payable for GS–18 of the General Schedule under section 5332 of title 5;

(5) accept and use donations of property from Federal, State, and local government agencies;

(6) use the mails in the same manner as any other department or agency of the executive branch;

(7) monitor implementation of the National Drug Control Program, including—

(A) conducting program and performance audits and evaluations; and

(B) requesting assistance from the Inspector General of the relevant agency in such audits and evaluations;

(8) except to the extent that the Director's authority under this paragraph is limited in an annual appropriations Act, transfer funds appropriated to a National Drug Control Program agency account to a different National Drug Control Program agency account in an amount that does not exceed 2 percent of the amount appropriated to either account, upon advance approval of the Committees on Appropriations of each House of Congress; and

(9) in order to ensure compliance with the National Drug Control Program, issue to the head of a National Drug Control Program agency a funds control notice described in subsection (f)[1] of this section.

**(e) Personnel detailed to the Office**

(1) Notwithstanding any provision of chapter 43 of title 5, the Director shall perform the evaluation of the performance of any employee detailed to the Office of National Drug Control Policy for purposes of the applicable performance appraisal system established under such chapter for any rating period, or part thereof, that such employee is detailed to such office.

(2)(A) Notwithstanding any other provision of law, the Director may provide periodic bonus payments to any employee detailed to the Office of National Drug Control Policy.

(B) An amount paid under this paragraph to an employee for any period shall not be greater than 20 percent of the basic pay paid or payable to such employee for such period.

(C) Any payment under this paragraph to an employee shall be in addition to the basic pay of such employee.

(D) The aggregate amount paid during any fiscal year to an employee detailed to the Office of National Drug Control Policy as basic pay, awards, bonuses, and other compensation shall not exceed the annual rate payable at the end of such fiscal year for positions at level III of the Executive Schedule.

**(f) Funds control notices**

(1) A funds control notice may direct that all or part of an amount appropriated to the National Drug Control Program agency account be obligated by—

(A) months, fiscal year quarters, or other time periods; and

(B) activities, functions, projects, or object classes.

(2) An officer or employee of a National Drug Control Program agency shall not make or authorize an expenditure or obligation contrary to a funds control notice issued by the Director.

(3) In the case of a violation of paragraph (2) by an officer or employee of a National Drug Control Program agency, the head of the agency, upon the request of and in consultation with the Director, may subject the officer or employee to appropriate administrative discipline, including, when circumstances warrant, suspension from duty without pay or removal from office.

[1] See References in Text note below.

**(f)[2] Prohibition on political campaigning**

A Federal officer in the Office of National Drug Control Policy who is appointed by the President, by and with the advice and consent of the Senate, may not participate in Federal election campaign activities, except that such an official is not prohibited by this subsection from making contributions to individual candidates.

(Pub. L. 100–690, title I, § 1003, Nov. 18, 1988, 102 Stat. 4182; Pub. L. 103–322, title IX, §§ 90201, 90202, 90207, Sept. 13, 1994, 108 Stat. 1990, 1991, 1995.)

REPEAL OF SECTION

*For repeal of section on Sept. 30, 1997, see section 1506 of this title.*

REFERENCES IN TEXT

This title, referred to in subsec. (d)(1), is title I of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4181, which enacted this chapter, repealed sections 1103, 1111 to 1114, 1116, and 1201 to 1204 of this title, amended section 1115 of this title, sections 5312, 5314, and 5315 of Title 5, Government Organization and Employees, section 1105 of Title 31, Money and Finance, and section 402 of Title 50, War and National Defense, enacted provisions set out as notes under section 1501 of this title and section 509 of Title 28, Judiciary and Judicial Procedure, and repealed provisions set out as notes under section 1201 of this title. For complete classification of title I to the Code, see Tables.

Subsection (f) of this section, referred to in subsec. (d)(9), probably means the subsec. (f) added by section 90201(c)(2) of Pub. L. 103–322.

Level III of the Executive Schedule, referred to in subsec. (e)(2)(D), is set out in section 5314 of Title 5, Government Organization and Employees.

CODIFICATION

Section is comprised of section 1003 of Pub. L. 100–690. Subsec. (a)(3) of section 1003 amended section 402 of Title 50, War and National Defense, and subsec. (a)(4) of section 1003 amended sections 5312, 5314, and 5315 of Title 5, Government Organization and Employees.

AMENDMENTS

1994—Subsec. (b)(8). Pub. L. 103–322, § 90201(b), added par. (8).

Subsec. (c)(3)(B). Pub. L. 103–322, § 90201(d), inserted ''in whole or in part'' after ''adequacy of such request'' and substituted ''and, with respect to a request that is not certified as adequate to implement the objectives of the National Drug Control Strategy, include in the certification an initiative or funding level that would make the request adequate;'' for the semicolon after ''the request is submitted''.

Subsec. (c)(5) to (8). Pub. L. 103–322, § 90201(a), added par. (5) and redesignated former pars. (5) to (7) as (6) to (8), respectively.

Subsec. (d)(1). Pub. L. 103–322, § 90207, which directed the amendment of section ''1008(d)(1) of the National Narcotics Leadership Act of 1988'' by substituting ''up to 75 and such additional'' for ''such'', was executed by making the substitution in subsec. (d)(1) of this section, which is section 1003 of the National Narcotics Leadership Act of 1988, to reflect the probable intent of Congress.

Subsec. (d)(2). Pub. L. 103–322, § 90201(c)(1)(A), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''direct, with the concurrence of the Secretary of a department or head of an agency, the temporary reassignment within the Federal Government of personnel employed by such department or agency, in order to implement United States drug control policy;''.

Subsec. (d)(8), (9). Pub. L. 103–322, § 90201(c)(1)(B)–(D), added pars. (8) and (9).

Subsec. (f). Pub. L. 103–322, § 90202, added subsec. (f) relating to prohibition on political campaigning.

Pub. L. 103–322, § 90201(c)(2), added subsec. (f) relating to funds control notices.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

RESOURCES FOR CERTAIN DRUG CONTROL ACTIVITIES

Section 4803 of Pub. L. 100–690, which directed Director of National Drug Control Policy to review the drug control problem and make recommendations for additional resources for the problem, was repealed by Pub. L. 102–583, § 6(e)(1), Nov. 2, 1992, 106 Stat. 4933.

OPPOSITION TO LEGALIZATION AND PUBLIC AWARENESS

Sections 5011 and 5012 of Pub. L. 100–690 provided that:

''SEC. 5011. SENSE OF THE CONGRESS OPPOSING LEGALIZATION OF DRUGS.

''The Congress finds that legalization of illegal drugs, on the Federal or State level, is an unconscionable surrender in a war in which, for the future of our country and the lives of our children, there can be no substitute for total victory.

''SEC. 5012. PUBLIC AWARENESS CAMPAIGN.

''The Director of National Drug Control Policy shall within 90 days after confirmation by the Senate develop a program to inform the American public of the provisions of this Act [see Short Title note set out under section 1501 of this title] pertaining to penalties for the use or possession of illegal drugs.''

UNITED STATES POLICY FOR A DRUG-FREE AMERICA BY 1995

Section 5251 of Pub. L. 100–690 provided that:

''(a) FINDINGS.—The Congress finds that—

''(1) approximately 37 million Americans used an illegal drug in the past year and more than 23 million Americans use illicit drugs at least monthly, including more than 6 million who use cocaine;

''(2) half of all high school seniors have used illegal drugs at least once, and over 25 percent use drugs at least monthly;

''(3) illicit drug use adds enormously to the national cost of health care and rehabilitation services;

''(4) illegal drug use can result in a wide spectrum of extremely serious health problems, including disruption of normal heart rhythm, small lesions of the heart, high blood pressure, leaks of blood vessels in the brain, bleeding and destruction of brain cells, permanent memory loss, infertility, impotency, immune system impairment, kidney failure, and pulmonary damage, and in the most serious instances, heart attack, stroke, and sudden death;

''(5) approximately 25 percent of all victims of AIDS acquired the disease through intravenous drug use;

''(6) over 30,000 people were admitted to emergency rooms in 1986 with drug-related health problems, including nearly 10,000 for cocaine alone;

''(7) there is a strong link between teenage suicide and use of illegal drugs;

''(8) 10 to 15 percent of all highway fatalities involve drug use;

''(9) illegal drug use is prevalent in the workplace and endangers fellow workers, national security, public safety, company morale, and production;

''(10) it is estimated that 1 of every 10 American workers have their productivity impaired by substance abuse;

[2] So in original. Probably should be ''(g)''.

''(11) it is estimated that drug users are 3 times as likely to be involved in on-the-job accidents, are absent from work twice as often, and incur 3 times the average level of sickness costs as non-users;

''(12) the total cost to the economy of drug use is estimated to be over $100,000,000,000 annually;

''(13) the connection between drugs and crime is also well-proven;

''(14) the use of illicit drugs affects moods and emotions, chemically alters the brain, and causes loss of control, paranoia, reduction of inhibition, and unprovoked anger;

''(15) drug-related homicides are increasing dramatically across the Nation;

''(16) 8 of 10 men arrested for serious crimes in New York City test positive for cocaine use;

''(17) illicit drug use is responsible for a substantially higher tax rate to pay for local law enforcement protection, interdiction, border control, and the cost of investigation, prosecution, confinement, and treatment;

''(18) substantial increases in funding and resources have been made available in recent years to combat the drug problem, with spending for interdiction, law enforcement, and prevention programs up by 100 to 400 percent and these programs are producing results—

''(A) seizures of cocaine are up from 1.7 tons in 1981 to 70 tons in 1987;

''(B) seizures of heroin are up from 460 pounds in 1981 to 1,400 pounds in 1987;

''(C) Drug Enforcement Administration drug convictions doubled between 1982 and 1986; and

''(D) the average sentence for Federal cocaine convictions rose by 35 percent during this same period;

''(19) despite the impressive rise in law enforcement efforts, the supply of illegal drugs has increased in recent years;

''(20) the demand for drugs creates and sustains the illegal drug trade; and

''(21) winning the drug war not only requires that we do more to limit supply, but that we focus our efforts to reduce demand.

''(b) DECLARATION.—It is the declared policy of the United States Government to create a Drug-Free America by 1995.''

NATIONAL COMMISSION ON MEASURED RESPONSES TO ACHIEVE A DRUG-FREE AMERICA BY 1995

Section 7604 of Pub. L. 100–690 provided for establishment of a Commission, to be chaired by the Director of the Office of National Drug Control Policy, which was to develop a proposed uniform code of State laws representing measured responses to achieve a Drug-Free America by 1995, and to submit its proposed uniformed code to the Governors of the 50 States and the Mayor of the District of Columbia within 6 months after appointment of the Commission's members. It was the sense of Congress that the Governors and the Mayor convene State conferences for a Drug-Free America by 1995 to consider the proposed uniform code and make recommendations thereon.

EX. ORD. NO. 12880. NATIONAL DRUG CONTROL PROGRAM

Ex. Ord. No. 12880, Nov. 16, 1993, 58 F.R. 60989, provided:

The Office of National Drug Control Policy has the lead responsibility within the Executive Office of the President to establish policies, priorities, and objectives for the Nation's drug control program, with the goal of reducing the production, availability, and use of illegal drugs. All lawful and reasonable means must be used to ensure that the United States has a comprehensive and effective National Drug Control Strategy.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, including the National Narcotics Leadership Act of 1988, as amended (21 U.S.C. 1501 *et seq.*), and in order to provide for the effective management of the drug abuse policies of the United States, it is hereby ordered as follows:

SECTION 1. GENERAL PROVISIONS. (a) Because the United States considers the operations of international criminal narcotics syndicates as a national security threat requiring an extraordinary and coordinated response by civilian and military agencies involved in national security, the Director of the Office of National Drug Control Policy (Director), in his role as the principal adviser to the National Security Council on national drug control policy (50 U.S.C. 402(f)), shall provide drug policy guidance and direction in the development of related national security programs.

(b) The Director shall provide oversight and direction for all international counternarcotics policy development and implementation, in coordination with other concerned Cabinet members, as appropriate.

(c) An Interagency Working Group (IWG) on international counternarcotics policy, chaired by the Department of State, shall develop and ensure coordinated implementation of an international counternarcotics policy. The IWG shall report its activities and differences of views among agencies to the Director for review, mediation, and resolution with concerned Cabinet members, and if necessary, by the President.

(d) A coordinator for drug interdiction shall be designated by the Director to ensure that assets dedicated by Federal drug program agencies for interdiction are sufficient and that their use is properly integrated and optimized. The coordinator shall ensure that interdiction efforts and priorities are consistent with overall U.S. international counternarcotics policy.

(e) The Director shall examine the number and structure of command/control and drug intelligence centers operated by drug control program agencies involved in international counter-narcotics and suggest improvements to the current structure for consideration by the President and concerned members of the Cabinet.

(f) The Director, utilizing the services of the Drugs and Crime Data Center and Department of Justice Clearinghouse, shall assist in coordinating and enhancing the dissemination of statistics and studies relating to anti-drug abuse policy.

(g) The Director shall provide advice to agencies regarding ways to achieve efficiencies in spending and improvements to interagency cooperation that could enhance the delivery of drug control treatment and prevention services to the public. The Director may request agencies to provide studies, information, and analyses in support of this order.

SEC. 2. GOALS, DIRECTION, DUTIES AND RESPONSIBILITIES WITH RESPECT TO THE NATIONAL DRUG CONTROL PROGRAM. (a) *Budget Matters.* (1) In addition to the budgetary authorities and responsibilities provided to the Director by statute, 21 U.S.C. 1502, for those agency budget requests that are not certified as adequate to implement the objectives of the National Drug Control Strategy, the Director shall include in such certifications initiatives or funding levels that would make such requests adequate.

(2) The Director shall provide, by July 1 of each year, budget recommendations to the heads of departments and agencies with responsibilities under the National Drug Control Program. The recommendations shall apply to the second following fiscal year and address funding priorities developed in the annual National Drug Control Strategy.

(b) *Measurement of National Drug Control Strategy Outcomes.* (1) The National Drug Control Strategy shall include long-range goals for reducing drug use and the consequences of drug use in the United States, including burdens on hospital emergency rooms, drug use among arrestees, the extent of drug-related crime, high school dropout rates, the number of infants exposed annually to illicit drugs in utero, national drug abuse treatment capacity, and the annual national health care costs of drug use.

(2) The National Drug Control Strategy shall also include an assessment of the quality of techniques and

instruments to measure current drug use and supply and demand reduction activities, and the adequacy of the coverage of existing national drug use instruments and techniques to measure the total illicit drug user population and groups at-risk for drug use.

(3) The Director shall coordinate an effort among the relevant drug control program agencies to assess the quality, access, management, effectiveness, and standards of accountability of drug abuse treatment, prevention, education, and other demand reduction activities.

(c) *Provision of Reports.* To the extent permitted by law, heads of departments and agencies with responsibilities under the National Drug Control Program shall make available to the Office of National Drug Control Policy, appropriate statistics, studies, and reports, pertaining to Federal drug abuse control.

WILLIAM J. CLINTON.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1504, 1505 of this title.

### § 1502a. Transferred

CODIFICATION

Section, Pub. L. 100–690, title I, § 1003A, as added Pub. L. 101–510, div. A, title X, § 1011, Nov. 5, 1990, 104 Stat. 1633 and amended, which related to the Counter-Drug Technology Assessment Center, was renumbered section 1008 of Pub. L. 100–690 by Pub. L. 103–322, title IX, § 90204(c)(2), (3), Sept. 13, 1994, 108 Stat. 1994, and is classified to section 1505 of this title.

### § 1503. Coordination with executive branch departments and agencies

#### (a) Access to information

(1) Upon request of the Director, and subject to laws governing disclosure of information, the head of each National Drug Control Program agency shall provide to the Director such information as may be required for drug control.

(2)(A) The authorities conferred on the Office of National Drug Control Policy and its Director by this Act shall be exercised in a manner consistent with provisions of the National Security Act of 1947. The Director of Central Intelligence shall prescribe such regulations as may be necessary to protect information provided pursuant to this Act regarding intelligence sources and methods.

(B) The Director of Central Intelligence shall, to the fullest extent possible in accordance with subparagraph (A), render full assistance and support to the Office of National Drug Control Policy and its Director.

#### (b) Certification of policy changes by Director

(1) The head of a National Drug Control Program agency shall, unless exigent circumstances require otherwise, notify the Director in writing regarding any proposed change in policies relating to the activities of such department or agency under the National Drug Control Program prior to implementation of such change. The Director shall promptly review such proposed change and certify to the department or agency head in writing whether such change is consistent with the National Drug Control Strategy.

(2) If prior notice of a proposed change under paragraph (1) is not possible, the department or agency head shall notify the Director as soon as practicable. The Director shall review such change and certify to the department or agency head in writing whether such change is consistent with the National Drug Control Program.

#### (c) General Services Administration

The Administrator of General Services shall provide to the Director on a reimbursable basis such administrative support services as the Director may request.

(Pub. L. 100–690, title I, § 1004, Nov. 18, 1988, 102 Stat. 4184.)

REPEAL OF SECTION

*For repeal of section on Sept. 30, 1997, see section 1506 of this title.*

REFERENCES IN TEXT

This Act, referred to in subsec. (a)(2)(A), is Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4181, known as the Anti-Drug Abuse Act of 1988. For complete classification of this Act to the Code, see Short Title note set out under section 1501 of this title and Tables.

The National Security Act of 1947, referred to in subsec. (a)(2)(A), is act July 26, 1947, ch. 343, 61 Stat. 495, as amended. For complete classification of this Act to the Code, see Short Title note set out under section 401 of Title 50, War and National Defense, and Tables.

### § 1504. Development and submission of National Drug Control Strategy

#### (a) Development and submission of National Drug Control Strategy

(1) Not later than 180 days after the first Director is confirmed by the Senate, and not later than February 1 of each year thereafter, the President shall submit to the Congress a National Drug Control Strategy. Any part of such strategy that involves information properly classified under criteria established by an Executive order shall be presented to the Congress separately.

(2) The National Drug Control Strategy submitted under paragraph (1) shall—

(A) include comprehensive, research-based, long-range goals for reducing drug abuse and the consequences of drug abuse in the United States;

(B) include short-term measurable objectives which the Director determines may be realistically achieved in the 2-year period beginning on the date of the submission of the strategy;

(C) describe the balance between resources devoted to supply reduction and demand reduction; and

(D) review State and local drug control activities to ensure that the United States pursues well-coordinated and effective drug control at all levels of government.

(3)(A) In developing the National Drug Control Strategy, the Director shall consult with—

(i) the heads of the National Drug Control Program agencies;

(ii) the Congress;

(iii) State and local officials;

(iv) private citizens with experience and expertise in demand reduction; and

(v) private citizens with experience and expertise in supply reduction.

(B) At the time the President submits the National Drug Control Strategy to the Congress, the Director shall transmit a report to the Congress indicating the persons consulted under this paragraph.

(4) The Director shall include with each National Drug Control Strategy an evaluation of the effectiveness of Federal drug control during the preceding year. The evaluation shall include an assessment of Federal drug control efforts, including—

(A) assessment of the reduction of drug use, including estimates of drug prevalence and frequency of use as measured by national, State, and local surveys of illicit drug use and by other special studies of—

(i) high-risk populations, including school dropouts, the homeless and transient, arrestees, parolees, and probationers, and juvenile delinquents; and

(ii) drug use in the workplace and the productivity lost by such use;

(B) assessment of the reduction of drug availability, as measured by—

(i) the quantities of cocaine, heroin, and marijuana available for consumption in the United States;

(ii) the amount of cocaine and heroin entering the United States;

(iii) the number of hectares of poppy and coca cultivated and destroyed;

(iv) the number of metric tons of heroin and cocaine seized;

(v) the number of cocaine processing labs destroyed;

(vi) changes in the price and purity of heroin and cocaine;

(vii) the amount and type of controlled substances diverted from legitimate retail and wholesale sources; and

(viii) the effectiveness of Federal technology programs at improving drug detection capabilities at United States ports of entry;

(C) assessment of the reduction of the consequences of drug use and availability, which shall include estimation of—

(i) burdens drug users placed on hospital emergency rooms in the United States, such as the quantity of drug-related services provided;

(ii) the annual national health care costs of drug use, including costs associated with people becoming infected with the human immunodeficiency virus and other communicable diseases as a result of drug use;

(iii) the extent of drug-related crime and criminal activity; and

(iv) the contribution of drugs to the underground economy, as measured by the retail value of drugs sold in the United States; and

(D) determination of the status of drug treatment in the United States, by assessing—

(i) public and private treatment capacity within each State, including information on the number of treatment slots available in relation to the number actually used, including data on intravenous drug users and pregnant women;

(ii) the extent, within each State, to which treatment is available, on demand, to intravenous drug users and pregnant women;

(iii) the number of drug users the Director estimates could benefit from treatment; and

(iv) the success of drug treatment programs, including an assessment of the effectiveness of the mechanisms in place federally, and within each State, to determine the relative quality of substance abuse treatment programs, the qualifications of treatment personnel, and the mechanism by which patients are admitted to the most appropriate and cost effective treatment setting.

(5) The Director shall include with the National Drug Control Strategy required to be submitted not later than February 1, 1995, and with every second such strategy submitted thereafter—

(A) an assessment of the quality of current drug use measurement instruments and techniques to measure supply reduction and demand reduction activities;

(B) an assessment of the adequacy of the coverage of existing national drug use measurement instruments and techniques to measure the casual drug user population and groups at-risk for drug use;

(C) an assessment of the actions the Director shall take to correct any deficiencies and limitations identified pursuant to subparagraphs (A) and (B); and

(D) identification of the specific factors that restrict the availability of treatment services to those seeking it and proposed administrative or legislative remedies to make treatment available to those individuals.

(6) Federal agencies responsible for the collection or estimation of drug-related information required by the Director shall cooperate with the Director, to the fullest extent possible, to enable the Director to satisfy the requirements of sections 4 and 5.[1]

(7) With each National Drug Control Strategy, the Director shall report to the President and the Congress on the Director's assessment of drug use and availability in the United States, including an estimate of the effectiveness of interdiction, treatment, prevention, law enforcement, and international programs under the National Drug Control Strategy in effect in the preceding year in reducing drug use and availability.

**(b) Goals, objectives, and priorities**

Each National Drug Control Strategy shall include—

(1) a complete list of goals, objectives, and priorities for supply reduction and for demand reduction;

(2) private sector initiatives and cooperative efforts between the Federal Government and State and local governments for drug control;

(3) 3-year projections for program and budget priorities and achievable projections for reductions of drug availability and usage;

(4) a complete assessment of how the budget proposal transmitted under section 1502(c) of this title is intended to implement the strategy and whether the funding levels contained in such proposal are sufficient to implement such strategy;

(5) designation of areas of the United States as high intensity drug trafficking areas in ac-

[1] So in original. Probably should be "paragraphs (4) and (5)."

cordance with subsection (c) of this section; and

(6) a plan for improving the compatibility of automated information and communication systems to provide Federal agencies with timely and accurate information for purposes of this subtitle.

**(c) High intensity drug trafficking areas**

(1) The Director, upon consultation with the Attorney General, heads of National Drug Control Program agencies, and the Governors of the several States, may designate any specified area of the United States as a high intensity drug trafficking area. After making such a designation and in order to provide Federal assistance to the area so designated, the Director may—

(A) direct the temporary reassignment of Federal personnel to such area, subject to the approval of the Secretary of the department or head of the agency which employs such personnel;

(B) take any other action authorized under section 1502 of this title to provide increased Federal assistance to such areas; and

(C) coordinate actions under this paragraph with State and local officials.

(2) When considering the designation of an area under this subsection as a high intensity drug trafficking area, the Director shall consider, along with other criteria the Director may deem appropriate—

(A) the extent to which the area is a center of illegal drug production, manufacturing, importation, or distribution;

(B) the extent to which State and local law enforcement agencies have committed resources to respond to the drug trafficking problem in the area, thereby indicating a determination to respond aggressively to the problem;

(C) the extent to which drug-related activities in the area are having a harmful impact in other areas of the country; and

(D) the extent to which a significant increase in allocation of Federal resources is necessary to respond adequately to drug-related activities in the area.

(3) Before March 1, 1991, the Director shall submit a report to the House of Representatives and to the Senate concerning the effectiveness of and need for the designation of areas under this subsection as high intensity drug trafficking areas, along with any comments or recommendations for legislation.

**(d) Lead agencies**

(1) The President shall designate lead agencies with areas of principal responsibility for carrying out the National Drug Control Strategy.

(2) The Director shall require that any National Drug Control Program agency that conducts a major supply reduction activity which is in the area of principal responsibility of a lead agency designated under paragraph (1) shall—

(A) notify such lead agency in writing of the activity; and

(B) provide such notification prior to conducting such activity, unless exigent circumstances require otherwise.

(3) If a lead agency objects to the conduct of an activity described under paragraph (2), the lead agency and the agency planning to conduct such activity shall notify the Director in writing regarding such objection.

(Pub. L. 100–690, title I, § 1005, Nov. 18, 1988, 102 Stat. 4185; Pub. L. 103–322, title IX, § 90203, Sept. 13, 1994, 108 Stat. 1991.)

REPEAL OF SECTION

*For repeal of section on Sept. 30, 1997, see section 1506 of this title.*

REFERENCES IN TEXT

This subtitle, referred to in subsec. (b)(6), is subtitle A of title I of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4181, known as the National Narcotics Leadership Act of 1988, which is classified principally to this chapter (§ 1501 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 1501 of this title and Tables.

AMENDMENTS

1994—Subsec. (a)(2)(A). Pub. L. 103–322, § 90203(1), inserted ''and the consequences of drug abuse'' after ''drug abuse''.

Subsec. (a)(4) to (7). Pub. L. 103–322, § 90203(2), amended par. (4) generally and added pars. (5) to (7). Prior to amendment, par. (4) read as follows: ''Beginning with the second submission of a National Drug Control Strategy, the Director shall include with each such strategy a complete evaluation of the effectiveness of drug control during the preceding year.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1502, 1507 of this title; title 42 sections 285*o*–4, 11903, 11904.

## § 1505. Counter-Drug Technology Assessment Center

**(a) Establishment**

There is established within the Office of National Drug Control Policy, the Counter-Drug Technology Assessment Center (hereinafter in this section referred to as the ''Center''). The Center shall operate under the authority of the Director of National Drug Control Policy and shall serve as the central counter-drug enforcement research and development organization of the United States Government.

**(b) Chief Scientist**

There shall be at the head of the Center the Chief Scientist of Counter-Drug Technology (hereinafter in this section referred to as the ''Chief Scientist''). The Chief Scientist shall be appointed by the Director of National Drug Control Policy from among individuals qualified and distinguished in the area of science, engineering, or technology.

**(c) Additional responsibilities of Director**

(1) The Director, acting through the Chief Scientist, shall—

(A) identify and define the short, medium, and long-term scientific and technological needs of Federal, State, and local drug enforcement agencies, including—

(i) advanced surveillance, tracking, and radar imaging;

(ii) electronic support measures;

(iii) communications;

(iv) data fusion, advanced computer systems and artificial intelligence; and

(v) chemical, biological, radiological (including neutron, electron, and graviton) and other means of detection;

(B) in consultation with the National Institute on Drug Abuse, and through interagency agreements or grants, examine addiction and rehabilitation research and the application of technology to expanding the effectiveness or availability of drug treatment;

(C) make a priority ranking of such needs according to fiscal and technological feasibility, as part of a National Counter-Drug Enforcement Research and Development Strategy;

(D) oversee and coordinate counter-drug technology initiatives with related activities of other Federal civilian and military departments; and

(E) under the general authority of the Director of National Drug Control Policy, submit requests to Congress for the reprogramming or transfer of funds appropriated for counter-drug enforcement research and development.

(2) The authority granted to the Director under this section shall not extend to the award of contracts, management of individual projects, or other operational activities.

**(d) Counter-drug budget submission**

Beginning with the budget submitted to Congress for fiscal year 1992 pursuant to section 1105 of title 31, the President shall submit a separate and detailed request relating to those Federal departments and agencies having responsibility for counter-drug enforcement research and development programs.

**(e) Personnel**

Subject to subsections (d) and (e) of section 1502 of this title, the Chief Scientist shall select and appoint a staff of not more than 10 employees with specialized experience in scientific, engineering, and technical affairs.

**(f) Assistance and support to Office of National Drug Control Policy**

The Director of the Advanced Research Project Agency shall, to the fullest extent possible, render assistance and support to the Office of National Drug Control Policy and its Director.

(Pub. L. 100–690, title I, § 1008, formerly § 1003A, as added Pub. L. 101–510, div. A, title X, § 1011, Nov. 5, 1990, 104 Stat. 1633; renumbered § 1008 and amended Pub. L. 103–322, title IX, § 90204(a), (b), (c)(2), (3), Sept. 13, 1994, 108 Stat. 1993, 1994.)

REPEAL OF SECTION

*For repeal of section on Sept. 30, 1997, see section 1506 of this title.*

CODIFICATION

Section was formerly classified to section 1502a of this title prior to renumbering by Pub. L. 103–322.

PRIOR PROVISIONS

A prior section 1505, Pub. L. 100–690, title I, § 1008, Nov. 18, 1988, 102 Stat. 4188, provided for an executive reorganization study and report to Congress and the President no later than Jan. 15, 1990, prior to repeal by Pub. L. 103–322, § 90204(c)(1).

AMENDMENTS

1994—Subsec. (c)(1)(B) to (E). Pub. L. 103–322, § 90204(a), added subpar. (B) and redesignated former subpars. (B) to (D) as (C) to (E), respectively.

Subsec. (f). Pub. L. 103–322, § 90204(b), added subsec. (f).

## § 1506. Termination of Office of National Drug Control Policy

This subtitle and the amendments made by this subtitle, other than section 1007, are repealed on September 30, 1997.

(Pub. L. 100–690, title I, § 1009, Nov. 18, 1988, 102 Stat. 4188; Pub. L. 103–322, title IX, § 90208(a), Sept. 13, 1994, 108 Stat. 1995.)

REFERENCES IN TEXT

This subtitle, referred to in text, is subtitle A of title I of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4181, known as the National Narcotics Leadership Act of 1988, which is classified principally to this chapter (§ 1501 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 1501 of this title and Tables.

Section 1007, referred to in text, is section 1007 of Pub. L. 100–690, title I, Nov. 18, 1988, 102 Stat. 4187, which amended section 1115 of this title and sections 5314 and 5315 of Title 5, Government Organization and Employees, repealed sections 1103, 1111 to 1114, 1116, and 1201 to 1204 of this title, enacted provisions set out as notes under section 1501 of this title, and repealed provisions set out as notes under section 1201 of this title.

AMENDMENTS

1994—Pub. L. 103–322 substituted ''September 30, 1997'' for ''the date which is 5 years after November 18, 1988''.

CONTINUED EFFECTIVENESS OF NATIONAL NARCOTICS LEADERSHIP ACT OF 1988

Section 90208(b) of Pub. L. 103–322 provided that: ''The National Narcotics Leadership Act of 1988 (21 U.S.C. 1501 et seq.) [see Short Title note set out under section 1501 of this title] shall be considered not to have been repealed by operation of section 1009 of that Act [this section], but shall remain in effect as if the amendment made by subsection (a) [amending this section] had been included in that Act on the date of its enactment [Nov. 18, 1988].''

## § 1507. Definitions

As used in this subtitle—

(1) the term ''drug'' has the same meaning as the term ''controlled substance'' has in section 802(6) of this title;

(2) the term ''drug control'' means any activity conducted by a National Drug Control Program agency involving supply reduction or demand reduction;

(3) the term ''supply reduction'' means any enforcement activity of a program conducted by a National Drug Control Program agency that is intended to reduce the supply or use of drugs in the United States and abroad, including—

(A) international drug control;

(B) foreign and domestic drug enforcement intelligence;

(C) interdiction; and

(D) domestic drug law enforcement, including law enforcement directed at drug users;

(4) the term ''demand reduction'' means any activity conducted by a National Drug Control Program agency, other than an enforcement activity, that is intended to reduce the demand for drugs, including—

(A) drug abuse education;

(B) prevention;
(C) treatment;
(D) research; and
(E) rehabilitation;

(5) the term ''National Drug Control Program'' means programs, policies, and activities undertaken by National Drug Control Program agencies pursuant to the responsibilities of such agencies under the National Drug Control Strategy;

(6) the term ''National Drug Control Program agency'' means any department or agency and all dedicated units thereof, with responsibilities under the National Drug Control Strategy, as designated—

(A) jointly by the Director and the head of the department or agency; or
(B) by the President;

(7) the term ''Director'' means the Director of National Drug Control Policy; and

(8) the term ''National Drug Control Strategy'' means a strategy developed and submitted to the Congress under section 1504 of this title.

(Pub. L. 100–690, title I, § 1010, Nov. 18, 1988, 102 Stat. 4188.)

REPEAL OF SECTION

*For repeal of section on Sept. 30, 1997, see section 1506 of this title.*

REFERENCES IN TEXT

This subtitle, referred to in text, is subtitle A of title I of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4181, known as the National Narcotics Leadership Act of 1988, which is classified principally to this chapter (§ 1501 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 1501 of this title and Tables.

## § 1508. Authorization of appropriations

For the purposes of carrying out this subtitle, there are authorized to be appropriated $3,500,000 for fiscal year 1989 and such sums as may be necessary for each of the 8 succeeding fiscal years, to remain available until expended.

(Pub. L. 100–690, title I, § 1011, Nov. 18, 1988, 102 Stat. 4189; Pub. L. 103–322, title IX, § 90206, Sept. 13, 1994, 108 Stat. 1995.)

REPEAL OF SECTION

*For repeal of section on Sept. 30, 1997, see section 1506 of this title.*

REFERENCES IN TEXT

This subtitle, referred to in text, is subtitle A of title I of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4181, known as the National Narcotics Leadership Act of 1988, which is classified principally to this chapter (§ 1501 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 1501 of this title and Tables.

AMENDMENTS

1994—Pub. L. 103–322 substituted ''8 succeeding fiscal years'' for ''4 succeeding fiscal years''.

APPROPRIATIONS

Provisions appropriating funds for fiscal year 1994 for necessary expenses of Office of National Drug Control Policy and requiring the Office to hire and maintain not less than 40 full-time equivalent positions were contained in the Executive Office Appropriations Act, 1994, Pub. L. 103–123, title III, Oct. 28, 1993, 107 Stat. 1235, 1237.

## § 1509. Establishment of Special Forfeiture Fund

### (a) In general

There is established in the Treasury of the United States the Special Forfeiture Fund (hereafter referred to in this section as the ''Fund'') which shall be available to the Director of the National Drug Control Policy without fiscal year limitation in such amounts as may be specified in appropriations Acts.

### (b) Deposits

There shall be deposited into the Fund the amounts specified by section 524(c)(9) of title 28 and section 9307(g)[1] of title 31 and any earnings on the investments authorized by subsection (d) of this section.

### (c) Super surplus

(1) Any unobligated balance up to $20,000,000 remaining in the Fund on September 30 of a fiscal year shall be available to the Director, subject to paragraph (2), to transfer to, and for obligation and expenditure in connection with drug control activities of, any Federal agency or State or local entity with responsibilities under the National Drug Control Strategy.

(2) A transfer may be made under paragraph (1) only with the advance written approval of the Committees on Appropriations of each House of Congress.

### (d) Investment of Fund

Amounts in the Fund which are not currently needed for the purposes of this section shall be kept on deposit or invested in obligations of, or guaranteed by, the United States and all earnings on such investments shall be deposited in the Fund.

### (e) President's budget

The President shall, in consultation with the Director for National Drug Control Policy, include, as part of the budget submitted to the Congress under section 1105(a) of title 31, a separate and detailed request for the use of the amounts in the Fund. This request shall reflect the priorities of the National Drug Control strategy.[2]

### (f) Funds provided supplemental

Funds disbursed under this subsection[3] shall not be used to supplant existing funds, but shall be used to supplement the amount of funds that would be otherwise available.

### (g) Annual report

No later than 4 months after the end of each fiscal year, the President shall submit to both Houses of Congress a detailed report on the amounts deposited in the Fund and a description of expenditures made under this subsection.[3]

(Pub. L. 100–690, title VI, § 6073, Nov. 18, 1988, 102 Stat. 4323; Pub. L. 101–647, title XX, § 2001(b),

[1] See References in Text note below.
[2] So in original. Probably should be capitalized.
[3] So in original. Probably should be ''section''.

Nov. 29, 1990, 104 Stat. 4854; Pub. L. 102–393, title VI, § 638(c), Oct. 6, 1992, 106 Stat. 1788; Pub. L. 103–322, title IX, § 90205(a), (d), Sept. 13, 1994, 108 Stat. 1994, 1995.)

REFERENCES IN TEXT

Section 9307(g) of title 31, referred to in subsec. (b), probably should be a reference to section 9703(g) of title 31, and probably means the section 9703 of title 31 added by section 638(b)(1) of Pub. L. 102–393.

CODIFICATION

Section was enacted as part of the Anti-Drug Abuse Act of 1988 and as part of the Asset Forfeiture Amendments Act of 1988, and not as part of the National Narcotics Leadership Act of 1988 which comprises this chapter.

AMENDMENTS

1994—Subsec. (b). Pub. L. 103–322, § 90205(a), which directed that this section be amended to read as follows, was executed by amending subsec. (b) of this section generally, to reflect the probable intent of Congress. Prior to amendment, subsec. (b) read as follows: ''There may be transferred to and deposited into the Special Forfeiture Fund, amounts from—

''(1) the Department of Justice Assets Forfeiture Fund pursuant to section 524(c)(9) of title 28; and

''(2) the Department of the Treasury Forfeiture Fund pursuant to section 9703(g)(3)(A) of title 31.''

Subsecs. (c) to (g). Pub. L. 103–322, § 90205(d), added subsec. (c) and redesignated former subsecs. (c) to (f) as (d) to (g), respectively.

1992—Subsec. (b). Pub. L. 102–393 amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''Deposits in the Fund shall be made by transfer from the Department of Justice Assets Forfeiture Fund in the manner provided in section 524(c)(9) of title 28.''

1990—Subsec. (b). Pub. L. 101–647 amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''Beginning in fiscal year 1990, there shall be deposited in the Fund not to exceed $150,000,000 in unobligated amounts remaining at the end of each fiscal year from the Department of Justice Assets Forfeiture Fund (28 U.S.C. 524(c)) except that amounts specified in section 524(c)(9) of title 28 may be carried forward and remain available for appropriation in the next fiscal year.''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 28 section 524; title 31 section 9703.