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].''

## § 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 Pub. L. 87–781, title I, § 113, Oct. 10, 1962, 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

(1) 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 shall register with the Secretary his name, places of business, and all such establishments.

(2) During the period beginning on October 1 and ending on 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 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) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or

(5) 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.

In this subsection, the term ''wholesale distributor'' means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

**(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, or by persons accredited to conduct inspections under section 374(g) of this title, 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) Registration of foreign establishments**

(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

(A) upon first engaging in any such activity, immediately register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation; and

(B) each establishment subject to the requirements of subparagraph (A) shall thereafter—

(i) with respect to drugs, register with the Secretary on or before December 31 of each year; and

(ii) with respect to devices, register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.

(2) The establishment shall also provide the information required by subsection (j) of this section.

(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), 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), (d), or (i) 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 section 355 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 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, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, 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 or person who is accredited under section 360m(a) of this title (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.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 282(j)(1) of title 42) shall be accompanied by the certification required under section 282(j)(5)(B) of such title. Such certification shall not be considered an element of such notification.

***(l)* Exemption from reporting requirements**

A report under subsection (k) of this section is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) of this section or is within a type that has been classified into class I under section 360c of this title. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

**(m) List of exempt class II devices; determination by Secretary; publication in Federal Register**

(1) Not later than 60 days after November 21, 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) of this section to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report under subsection (k) of this section as of the date of the publication of the list in the Federal Register. The Secretary shall publish such list on the Internet site of the Food and Drug Administration. The list so published shall be updated not

later than 30 days after each revision of the list by the Secretary.

(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the requirement to submit a report under subsection (k) of this section, upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

**(n) Review of report; time for determination by Secretary**

The Secretary shall review the report required in subsection (k) of this section and make a determination under section 360c(f)(1) of this title not later than 90 days after receiving the report.

**(*o*) Reprocessed single-use devices**

(1) With respect to reprocessed single-use devices for which reports are required under subsection (k) of this section:

(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within six months after October 26, 2002, the Secretary shall publish in the Federal Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) of this section for devices or types of devices within a type included on the list are, upon publication of the list, required to include such validation data.

(B) In the case of each report under subsection (k) of this section that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) of this section shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this chapter against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 352(*o*) of this title or adulterated under section 351(f)(1)(B) of this title, or take action against the device under section 331(p) of this title for failure to provide any information required by subsection (k) of this section until (i) the review is terminated by withdrawal of the submission of the report under subsection (k) of this section; (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

(C) In the case of a report under subsection (k) of this section for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

(D) Section 352(*o*) of this title applies with respect to the failure of a report under subsection (k) of this section to include validation data required under subparagraph (A).

(2) With respect to critical or semi-critical reprocessed single-use devices that, under subsection (*l*) or (m) of this section, are exempt from the requirement of submitting reports under subsection (k) of this section:

(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is terminated upon the publication of the list. For each report under subsection (k) of this section submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) of this section shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this chapter against such device solely on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 352(*o*) of this title or adulterated under section 351(f)(1)(B) of this title, or take action against the device under section 331(p) of this title for failure to provide any information required by subsection (k) of this section until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to

a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

(C) In the case of semi-critical devices, the initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection. In the case of critical devices, the initial list under such subparagraph shall be published not later than six months after such effective date.

(D) Section 352(*o*) of this title applies with respect to the failure to submit a report under subsection (k) of this section that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

(E) The termination under subparagraph (A) of an exemption under subsection (*l*) or (m) of this section for a critical or semi-critical reprocessed single-use device does not terminate the exemption under subsection (*l*) or (m) of this section for the original device.

**(p) Electronic registration**

Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

(June 25, 1938, ch. 675, § 510, as added Pub. L. 87–781, title III, § 302, Oct. 10, 1962, 76 Stat. 794; amended Pub. L. 89–74, § 4, July 15, 1965, 79 Stat. 231; Pub. L. 91–513, title II, § 701(e), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 92–387, §§ 3, 4(a)–(c), Aug. 16, 1972, 86 Stat. 560–562; Pub. L. 94–295, § 4(a), May 28, 1976, 90 Stat. 579; Pub. L. 105–115, title I, § 125(a)(2)(C), title II, §§ 206(a), 209(a), 213(b), title IV, § 417, Nov. 21, 1997, 111 Stat. 2325, 2338, 2341, 2347, 2379; Pub. L. 107–188, title III, § 321(a), June 12, 2002, 116 Stat. 675; Pub. L. 107–250, title II, §§ 201(e), 207, 211, title III, § 302(b), Oct. 26, 2002, 116 Stat. 1609, 1613, 1614, 1616; Pub. L. 108–214, § 2(c)(2), Apr. 1, 2004, 118 Stat. 576; Pub. L. 110–85, title II, §§ 222–224, title VIII, § 801(b)(3)(C), Sept. 27, 2007, 121 Stat. 853, 921.)

REFERENCES IN TEXT

The effective date of this subsection, referred to in subsec. (*o*)(2)(C), probably means the date of the enactment of Pub. L. 107–250, which enacted subsec. (*o*) of this section and was approved Oct. 26, 2002.

AMENDMENTS

2007—Subsec. (b). Pub. L. 110–85, § 222(a), designated existing provisions as par. (1), struck out ''or a device or devices'' after ''drug or drugs'', and added par. (2).

Subsec. (i)(1). Pub. L. 110–85, § 222(b), inserted text of par. (1) and struck out former text of par. (1) which related to registration requirement for foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device to be imported or offered for import into the United States.

Subsec. (j)(2). Pub. L. 110–85, § 223, in introductory provisions, substituted ''Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:'' for ''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:''.

Subsec. (k). Pub. L. 110–85, § 801(b)(3)(C), inserted concluding provisions.

Subsec. (p). Pub. L. 110–85, § 224, amended subsec. (p) generally. Prior to amendment, subsec. (p) read as follows: ''Registrations under subsections (b), (c), (d), and (i) of this section (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Secretary that the electronic receipt of such registrations is feasible, unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.''

2004—Subsec. (*o*)(1)(B), (2)(B). Pub. L. 108–214, § 2(c)(2)(A), (B)(i), substituted ''or adulterated'' for '', adulterated''.

Subsec. (*o*)(2)(E). Pub. L. 108–214, § 2(c)(2)(B)(ii), substituted ''semi-critical'' for ''semicritical''.

2002—Subsec. (h). Pub. L. 107–250, § 201(e), inserted '', or by persons accredited to conduct inspections under section 374(g) of this title,'' after ''duly designated by the Secretary''.

Subsec. (i)(1). Pub. L. 107–188, § 321(a)(1), substituted ''On or before December 31 of each year, any establishment'' for ''Any establishment'' and ''shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation'' for ''shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment''.

Subsec. (j)(1). Pub. L. 107–188, § 321(a)(2), substituted ''subsection (b), (c), (d), or (i)'' for ''subsection (b), (c), or (d)'' in first sentence.

Subsec. (m)(1). Pub. L. 107–250, § 211, inserted at end ''The Secretary shall publish such list on the Internet site of the Food and Drug Administration. The list so published shall be updated not later than 30 days after each revision of the list by the Secretary.''

Subsec. (*o*). Pub. L. 107–250, § 302(b), added subsec. (*o*).

Subsec. (p). Pub. L. 107–250, § 207, added subsec. (p).

1997—Subsec. (g). Pub. L. 105–115, § 213(b)(3), inserted at end ''In this subsection, the term 'wholesale distributor' means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''

Subsec. (g)(4), (5). Pub. L. 105–115, § 213(b)(1), (2), added par. (4) and redesignated former par. (4) as (5).

Subsec. (i). Pub. L. 105–115, § 417, amended subsec. (i) generally. Prior to amendment, subsec. (i) read as follows: ''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.''

Subsec. (j)(1)(A), (D). Pub. L. 105–115, §125(a)(2)(C), struck out '', 356, 357,'' before ''or 360b of this title''.

Subsec. (k). Pub. L. 105–115, §206(a)(1), inserted ''or person who is accredited under section 360m(a) of this title'' after ''report to the Secretary''.

Subsecs. (*l*), (m). Pub. L. 105–115, §206(a)(2), added subsecs. (*l*) and (m).

Subsec. (n). Pub. L. 105–115, §209(a), added subsec. (n).

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 2002 AMENDMENT

Amendment by Pub. L. 107–188 effective upon the expiration of the 180-day period beginning June 12, 2002, see section 321(c) of Pub. L. 107–188, set out as a note under section 331 of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by sections 206(a), 209(a), 213(b), and 417 of Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of this title.

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.

## § 360a. Clinical trial guidance for antibiotic drugs

### (a) In general

Not later than 1 year after September 27, 2007, the Secretary shall issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. Such guidance shall indicate the appropriate models and valid surrogate markers.

### (b) Review

Not later than 5 years after September 27, 2007, the Secretary shall review and update the guidance described under subsection (a) to reflect developments in scientific and medical information and technology.

(June 25, 1938, ch. 675, § 511, as added Pub. L. 110–85, title IX, § 911, Sept. 27, 2007, 121 Stat. 951.)

PRIOR PROVISIONS

A prior section 360a, 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, prior to repeal by Pub. L. 91–513, title II, §§ 701(a), 704, Oct. 27, 1970, 84 Stat. 1281, 1284, effective on the first day of the seventh calendar month that began after Oct. 26, 1970.

## § 360b. New animal drugs

### (a) Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research; import tolerances

(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purposes of section 351(a)(5) of this title and section 342(a)(2)(C)(ii) 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 such drug, its labeling, and such use conform to such approved application;

(B) there is in effect a conditional approval of an application filed pursuant to section 360ccc of this title with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such conditionally approved application; or

(C) there is in effect an index listing pursuant to section 360ccc–1 of this title with respect to such use or intended use of such drug in a minor species, and such drug, its labeling, and such use conform to such index listing.

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