§ 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(a)(b), 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 to 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 re-
fuses 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 previously been instituted or become final under subsection (f) of this section.

(h) Guidance documents
(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidance without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

(C) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of such comment into account.

(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

(5) Not later than July 1, 2000, the Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.

(Amendment)

ucts regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple syrup (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 Secretary, for provisions which permitted service of summons and petition any place in United States and Secretary, for provisions which permitted service of summons and petition any place in United States and Secretary, for provisions which permitted service of summons and petition any place in United States and Secretary.

EXEMPTIONS FOR NEW FOODS, PREPARED OR PROCESSED FOODS, AND NUTRITIONAL SUPPLEMENTS

CHAPTER 2—FOOD AND NUTRITIONAL SUPPLEMENTS

§ 372. Examinations and investigations

(a) Authority to conduct

(1)(A) 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.

(B) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this chapter.

(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this chapter in Indian country without the express written consent of the Indian tribe involved.

(2)(A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Sec-
the head of such department or agency shall
with respect to their respective departments or
agencies submit to the committees of jurisdic-
tion (authorizing and appropriating) in the
House of Representatives and the Senate a re-
port that provides, for such year—
(i) the number of officers or employees that
were inspected or examined as a result of such
memorandum; and
(ii) the number of additional examinations
or inspections that were carried out pursuant
to such memorandum.
(3) In the case of food packed in the Common-
wealth of Puerto Rico or a Territory the Sec-
retary 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
such inspection.
(4) 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 sam-

dles
Where a sample of a food, drug, or cosmetic is
collected for analysis under this chapter the Sec-
retary 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 regu-
lations, to make such reasonable exceptions
from, and impose such reasonable terms and condi-
tions relating to, the operation of this sub-
section as he finds necessary for the proper ad-
ministration 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 estab-
lishment in the executive branch of the Govern-
ment shall be open to inspection by any official of the Department duly authorized by the Sec-
retary to make such inspection.

(d) Information on patents for drugs
The Secretary is authorized and directed, upon
request from the Under Secretary of Commerce for Intellectual Property and Director of the
United States Patent and Trademark Office, to
turn full and complete information with re-
spect to such questions relating to drugs as the
Director may submit concerning any patent ap-
lication. 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 exami-
inations, 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 ar-
rest warrants;
(3) execute seizure by process issued pursuant
to libel under section 334 of this title;
(4) make arrests without warrant for of-
fenses under this chapter with respect to such
drugs if the offense is committed in his pres-
ence or, in the case of a felony, if he has prob-
able cause to believe that the person so ar-
rested 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 equip-
ment, punches, dies, plates, stones, labeling,
or other things, if they are, or he has rea-
sonable grounds to believe that they are, sub-
ject 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 in-
stituted promptly and the property seized
be placed under the jurisdiction of the court.

Amendments
2009—Subsec. (a)(1). Pub. L. 111–31 designated existing provisions as subpar. (A) and added subpar. (B).
(2), inserted “(3)” before “in the case of food packed”, and substituted “(4) For the purposes of this sub-
section,” for “For the purposes of this subsection”. 


1992—Subsec. (c). Pub. L. 102-300, which directed the amendment of subsection (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 references to depressant or stimulant drugs.

1965—Subsec. (c). Pub. L. 89-74 substituted “the Commonwealth of Puerto Rico or” before “a Territory the Secretary”.

Effective Date of 1999 Amendment
Amendment by Pub. L. 106-113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106-113, 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 701 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

Effective Date of 1965 Amendment

Savings Provision
Amendment by Pub. L. 91-513 not to affect or abate any proceedings 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 Administration 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 331 of this title.

§ 372a. Transferred

Codification

§ 373. Records

(a) In general

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, tobacco products, 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, tobacco product, 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, tobacco product, 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, tobacco products, or cosmetics in the usual course of business as carriers, except as provided in subsection (b) of this section.

(b) Food transportation records

A shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 350e of this title shall, on request of an officer or employee designated by the Secretary, permit the officer or employee, at reasonable times, to have access to and to copy all records that the Secretary requires to be kept under section 350e(c)(1)(E) of this title.


Amendments


2005—Pub. L. 109-59 struck out “of interstate shipment” after “Records” in section catchline, designated existing provisions as subsec. (a), inserted subsec. heading, substituted “carriers, except as provided in subsection (b) of this section” for “carriers” before period at end, and added subsec. (b).

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 2005 Amendment

Effective Date of 1970 Amendment
Amendment by Pub. L. 91-452 effective on sixty-fifth 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 sixty-fifth day following Oct. 15, 1970, see section 205 of Pub. L. 91-452, set out as an Effective Date; Savings Provision note under section 6001 of Title 18, Crimes and Criminal Procedure.
TRANFER OF FUNCTIONS

For transfer of functions of Federal Security Admin-
istrator 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 notes set out under
section 321 of this title.

§ 374. Inspection

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions

(1) For purposes of enforcement of this chap-
ter, officers or employees duly designated by the
Secretary, upon presenting appropriate creden-
tials and a written notice to the owner, opera-
tor, or agent in charge, are authorized (A) to
enter, at reasonable times, any factory, ware-
house, or establishment in which food, drugs, de-
vices, tobacco products, or cosmetics are manu-
factured, processed, packed, or held, for intro-
duction into interstate commerce or after such
introduction, or to enter any vehicle being used
to transport or hold such food, drugs, devices,
tobacco products, or cosmetics in interstate
commerce; and (B) to inspect, at reasonable
times and within reasonable limits and in a rea-
sonable manner, such factory, warehouse, estab-
ishment, or vehicle and all pertinent equip-
ment, finished and unfinished materials, con-
tainers, and labeling therein. In the case of any
person (excluding farms and restaurants) who
manufactures, processes, packs, transports, dis-
tributes, holds, or imports foods, the inspection
shall extend to all records and other informa-
tion described in section 350c of this title, when
the standard for records inspection under para-
graph (1) or (2) of section 350c(a) of this title ap-
plies, subject to the limitations established in
section 350c(d) of this title. In the case of any
factory, warehouse, establishment, or consult-
ing laboratory in which prescription drugs, non-
prescription drugs intended for human use, re-
stricted devices, or tobacco products are manu-
factured, processed, packed, or held, the inspec-
tion shall extend to all things therein (including
records, files, papers, processes, controls, and fa-
cilities) bearing on whether prescription drugs,
nonprescription drugs intended for human use,
restricted devices, or tobacco products which
are adulterated or misbranded within the mean-
ing of this chapter, or which may not be manu-
factured, introduced into interstate commerce,
or sold, or offered for sale by reason of any pro-
vision 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 au-
thorized by the preceding sentence or by para-
graph (3) shall extend to financial data, sales
data other than shipment data, pricing data,
personnel data (other than data as to qualifica-
tion of technical and professional personnel per-
forming functions subject to this chapter), and
research data (other than data relating to new
drugs, antibiotic drugs, devices, and tobacco
products and subject to reporting and inspection
under regulations lawfully issued pursuant to
section 355(i) or (k) of this title, section 360i of
this title, section 360j(g) of this title, or sub-
chapter IX and data relating to other drugs, de-
vices, or tobacco products which in the case of a
new drug would be subject to reporting or in-
spection under lawful regulations issued pursu-
ant to section 355(j) of this title). A separate no-
tice shall be given for each such inspection, but
a notice shall not be required for each entry
made during the period covered by the inspec-
tion. Each such inspection shall be commenced
and completed with reasonable promptness.

(2) The provisions of the third sentence of
paragraph (1) shall not apply to—

(A) pharmacies which maintain establish-
ments 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 busi-
ness of dispensing or selling drugs or devices
at retail;

(B) practitioners licensed by law to prescribe
or administer drugs, or prescribe or use de-
vices, as the case may be, and who manufac-
ture, prepare, propagate, compound, or process
drugs, or manufacture or process devices, sole-
ly for use in the course of their professional
practice;

(C) persons who manufacture, prepare, prop-
agate, compound, or process drugs or manufac-
ture or process devices, solely for use in re-
search, teaching, or chemical analysis and not
for sale;

(D) such other classes of persons as the Secre-
trary may by regulation exempt from the ap-
plication of this section upon a finding that
inspection as applied to such classes of persons
in accordance with this section is not nec-
essary for the protection of the public health.

(3) An officer or employee making an inspec-
tion under paragraph (1) for purposes of enforc-
ing 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
verify and copy 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 in-
spection 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, tobacco product, or cosmetic in
such establishment: (1) consists in whole or in
part of any filthy, putrid, or decomposed sub-
stance, or (2) has been prepared, packed, or held
under insanitary conditions whereby it may
have become contaminated with filth, or where-
by 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 360 or 360g 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.

(f) Recordkeeping

(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

(2) Within 15 days after the receipt of a written request from the Secretary to an accredited person described in paragraph (3) for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(3) For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—

(A) is accredited under subsection (g) of this section; or

(B) is accredited under section 360m of this title.

(g) Inspections by accredited persons

(1) The Secretary shall, subject to the provisions of this subsection, accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 360(h) of this title or are inspections of such establishments required to register under section 360(i) of this title. The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections.

(2) The Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at device establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited.

(3) An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this chapter and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this chapter.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will—

(i) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this chapter, and recommendations made during an inspection or at an inspection’s closing meeting;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the Secretary;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this chapter, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.
(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of a certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).

(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of persons who are accredited under paragraph (2). Such list shall be updated to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall (i) audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of a device establishment and the performance of accredited persons, and (ii) take such additional measures as the Secretary determines to be appropriate.

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation, poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection. The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

(i) The Secretary classified the results of the most recent inspection of the establishment as "no action indicated" or "voluntary action indicated".

(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

(iv) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(aa) at least 1 of such devices is marketed in the United States; and

(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

(I) denies clearance to participate as provided under subparagraph (C); or

(II) makes a request under clause (ii).

(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

(I) compliance data for the establishment in accordance with clause (iii)(I); or

(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

(iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 351(h) of this title and with other applicable provisions of this chapter. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(II) A request to an accredited person under clause (i)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the no-
tice under subparagraph (A)(i) for inspections of
the establishment unless the Secretary, not
later than 60 days after receiving the informa-
tion requested under clause (ii), issues a re-
sponse that denies clearance to participate as
provided under subparagraph (C).
(C)(i) The Secretary may deny clearance to a
device establishment if the Secretary has evi-
dence that the certification under subparagraph
(A)(ii)(IV) is untrue and the Secretary provides
to the owner or operator of the establishment a
statement summarizing such evidence.
(ii) The Secretary may deny clearance to a de-
vice establishment if the Secretary determines
that the establishment has failed to dem-
onstrate consistent compliance for purposes of
subparagraph (B)(iii)(I) and the Secretary pro-
vides to the owner or operator of the establish-
ment a statement of the reasons for such deter-
mination.
(iii)(I) The Secretary may reject the selection
of the accredited person identified in the notice
under subparagraph (A)(ii) if the Secretary pro-
vides to the owner or operator of the establish-
ment a statement of the reasons for such rejec-
tion. Reasons for the rejection may include that
the establishment or the accredited person, as
the case may be, has failed to fully respond to
the request, or that the Secretary has concerns
regarding the relationship between the estab-
lishment and such accredited person.
(II) If the Secretary rejects the selection of an
accredited person by the owner or operator of a
device establishment, the owner or operator
may make an additional selection of an accred-
ited person by submitting to the Secretary a no-
tice that identifies the additional selection.
Clauses (i) and (ii) of subparagraph (B), and sub-
clause (I) of this clause, apply to the selection of
an accredited person through a notice under the
preceding sentence in the same manner and to
the same extent as such provisions apply to a se-
lection of an accredited person through a notice
under subparagraph (A)(ii).
(iv) In the case of a device establishment that
is denied clearance under clause (i) or (ii) or with
respect to which the selection of the ac-
credited person is rejected under clause (iii), the
Secretary shall designate a person to review the
statement of reasons, or statement summarizing
such evidence, as the case may be, of the Sec-
rectary under such clause if, during the 30-day pe-
riod beginning on the date on which the owner
or operator of the establishment receives such
statement, the owner or operator requests the
review. The review shall commence not later
than 30 days after the owner or operator re-
quests the review, unless the Secretary and the
owner or operator otherwise agree.
(7)(A) Persons accredited under paragraph (2)
to conduct inspections shall record in writing
their inspection observations and shall present
the observations to the device establishment’s
designated representative and describe each ob-
servation. Additionally, such accredited person
shall prepare an inspection report in a form and
manner designated by the Secretary to conduct
inspections, taking into consideration the goals
of international harmonization of quality sys-
tems standards. Any official classification of the
inspection shall be determined by the Secretary.
(B) At a minimum, an inspection report under
subparagraph (A) shall identify the persons re-
ponsible for good manufacturing practice com-
pliance at the inspected device establishment,
the dates of the inspection, the scope of the in-
spection, and shall describe in detail each ob-
servation identified by the accredited person, iden-
tify other matters that relate to or may influ-
ence compliance with this chapter, and describe
any recommendations during the inspection or
at the inspection’s closing meeting.
(C) An inspection report under subparagraph
(A) shall be sent to the Secretary and to the des-
ignated representative of the inspected device
establishment at the same time, but under no
circumstances later than three weeks after the
last day of the inspection. The report to the Sec-
rectary shall be accompanied by all written in-
spection observations previously provided to the
designated representative of the establishment.
(D) Any statement or representation made by
an employee or agent of a device establishment
to a person accredited under paragraph (2) to
conduct inspections shall be subject to section
1001 of title 18.
(E) If at any time during an inspection by an
accredited person the accredited person discov-
ers a condition that could cause or contribute to
an unreasonable risk to the public health, the
accredited person shall immediately notify the
Secretary of the identification of the device estab-
lishment subject to inspection and such con-
dition.
(F) For the purpose of setting risk-based in-
spctional priorities, the Secretary shall accept
voluntary submissions of reports of audits as-
sessing conformance with appropriate quality
systems standards set by the International Or-
ganization for Standardization (ISO) and identi-
fied by the Secretary in public notice. If the
owner or operator of an establishment elects to
submit audit reports under this subparagraph,
the owner or operator shall submit all such
audit reports with respect to the establishment
during the preceding 2-year periods.
(8) Compensation for an accredited person
shall be determined by agreement between the
accredited person and the person who engages
the services of the accredited person, and shall
be paid by the person who engages such services.
(9) Nothing in this subsection affects the au-
thority of the Secretary to inspect any device
establishment pursuant to this chapter.
(10)(A) For fiscal year 2005 and each subse-
quent fiscal year, no device establishment may
be inspected during the fiscal year involved by a
person accredited under paragraph (2) if—
(i) of the amounts appropriated for salaries
and expenses of the Food and Drug Adminis-
tration for the preceding fiscal year (referred
to in this subparagraph as the “first prior fis-
tical year”), the amount obligated by the Sec-
rectary for inspections of device establishments
by the Secretary was less than the adjusted
base amount applicable to such first prior fis-
tical year; and
(ii) of the amounts appropriated for salaries
and expenses of the Food and Drug Adminis-
tration for the fiscal year preceding the first
prior fiscal year (referred to in this subpara-
graph as the “second prior fiscal year”), the

Page 314

§ 374

TITL E 21—FOOD AND DRUGS

573
amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such second prior fiscal year.

(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this subparagraph as the “compliance budget”); and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the “inspection budget”);

(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 360e of this title.

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a report describing the findings made through such determinations.

(C) For purposes of this paragraph:

(i) The term “base amount” means the inspection budget determined under subparagraph (B) for fiscal year 2002.

(ii) The term “adjusted base amount”, in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(iii) The term “adjusted base amount”, with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted base amount applicable to the preceding year increased by 5 percent.

(11) The authority provided by this subsection terminates on October 1, 2012.

(12) No later than four years after October 26, 2002, the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 360(b) of this title and of device establishments required to register under section 360(i) of this title;

(B) the number of persons who sought accreditation under this subsection, as well as the number of persons who were accredited under this subsection;

(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this chapter, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Secretary pursuant to inspections conducted by Federal employees;

(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for purposes of compliance with the laws of foreign governments; and

(G) whether the Congress should continue, modify, or terminate the program under this subsection.

(13) The Secretary shall include in the annual report required under section 393(g) of this title the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(14) Notwithstanding any provision of this subsection, this subsection does not have any legal effect on any agreement described in section 383(b) of this title between the Secretary and a foreign country.


Amendments

2011—Subsec. (a)(1). Pub. L. 111–332, which directed the amendment of subsec. (a)(1)(B) by substituting “section 350c of this title, when the standard for records inspection under paragraph (1) or (2) of section 350c(a) of this title applies, subject to” for “section 350c of this title when” and all that follows through “subject to”, was executed by making the substitution for “section 350c of this title when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to” in the sentence following subpar. (B) of subsec. (a)(1), to reflect the probable intent of Congress.

2009—Subsec. (a)(1). Pub. L. 111–31, §103(k)(1)(C), substituted “devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (k) of this title, section 360i of this title, section 360(g) of this title, or subchapter IX and data relating to other drugs, devices, or tobacco products” for “and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (k) of this title, section 360i of this title, section 360(g) of this title, and data relating to other drugs or devices”.

Pub. L. 111–31, §103(k)(1)(B), substituted “restricted devices, or tobacco products” for “or restricted devices” in two places.


Subsec. (g)(13). Pub. L. 111–31, §103(i)(3), made technical and conforming amendments to references in original act which appear in text as reference to section 393(g) of this title. 2007—Subsec. (g)(1). Pub. L. 110–85, §228(1), substituted “The Secretary” for “Not later than one year after October 26, 2002, the Secretary”.

Subsec. (g)(2). Pub. L. 110–85, §228(2), substituted “The Secretary” for “Not later than 180 days after October 26, 2002, the Secretary” and struck out at end “In the first year following the publication in the Federal Register of criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1), the Secretary shall accredit no more than 15 persons who request to perform duties specified in paragraph (1).”

Subsec. (g)(3)(F). (G). Pub. L. 110–85, §228(3), added subpars. (F) and (G).

Subsec. (g)(6). Pub. L. 110–85, §228(4), amended par. (6) generally, revising and restating provisions of former subpars. (A) to (C).

Subsec. (g)(7)(A). Pub. L. 110–85, §228(5)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: “Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment’s designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report (including for inspections classified as no action indicated) in a form and manner consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections.”


Subsec. (g)(10)(C)(iii). Pub. L. 110–85, §228(6), substituted “base amount applicable” for “based amount applicable.”

2004—Subsec. (g)(1). Pub. L. 108–214, §2(b)(1)(A), in first sentence, substituted “conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 360(h) of this title or inspections of such establishments required to register under section 360(i) of this title.” for “conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 360(h) of this title or inspections of such establishments required to register under section 360(i) of this title.”

Subsec. (g)(5)(B). Pub. L. 108–214, §2(b)(1)(B), in first sentence “poses a threat to public health,” fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection,” for “or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this subsection.”

Subsec. (g)(6)(A)(I). Pub. L. 108–214, §2(b)(1)(C)(I)(i), substituted “described in paragraph (1)” for “of the establishment pursuant to subsection (b) or (i) of section 360 of this title”.


Subsec. (g)(6)(A)(III). Pub. L. 108–214, §2(b)(1)(C)(II)(I), substituted “and 1 or both of the following additional conditions are met:” for “and the following additional conditions are met:” in introductory provisions.


tended for human use,” for “prescription drugs” in two places.

Pub. L. 105–115, §425(b)(2)(L), struck out “section 360j(g),” before “section 360i.”


1993—Subsec. (a)(1). Pub. L. 103–80 substituted a comma for semicolon after “finished and unfinished materials” and “section 355(1) or (2)” for “section 355(1) 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)” and “(B)” for “(1)” and “(2)”, respectively.


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, sold or held, inspections relating to devices, reporting and inspection regulations issued pursuant to sections 360i and 360j of this title, and the manufacture and processing of devices.


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).

§ 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, tobacco products, 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.


Codification

Section was enacted as a part of the Food Allergen Labeling and Consumer Protection Act of 2004, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 374a. Inspections relating to food allergens

The Secretary of Health and Human Services shall conduct inspections consistent with the authority under section 374 of this title of facilities in which foods are manufactured, processed, packed, or held—

(1) to ensure that the entities operating the facilities comply with practices to reduce or eliminate cross-contact of a food with residues of major food allergens that are not intentional ingredients of the food; and

(2) to ensure that major food allergens are properly labeled on foods.


Amendments


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 notes set out under section 321 of this title.
§ 376. Examination of seafood on request of packer; marking food with results; fees; penalties

The Secretary, upon application of any packer of any seafood 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.


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 1002(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


AMENDMENTS


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), July 12, 1980, 94 Stat. 685, which is classified to section 3509(b) of Title 20, Education.

For transfer of functions of Federal Security Administration 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 notes set out under section 321 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.


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 Administration 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 notes set out under section 321 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 439(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 preceding 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 makes 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.


References in Text

The Federal Trade Commission Act, referred to in subsection (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 38 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.

§ 379a. Presumption of existence of jurisdiction

In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.


AMENDMENTS


1997—Pub. L. 105–115 substituted “a device, food, drug, or cosmetic” for “a device”.

EFFECTIVE DATE OF 1997 AMENDMENT


§ 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 each fiscal year such sums as are necessary to carry out this section.


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.

§ 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.


§ 379d–1. Conflicts of interest

(a) Definitions

For purposes of this section:

(1) Advisory committee

The term “advisory committee” means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

(2) Financial interest

The term “financial interest” means a financial interest under section 208(a) of title 18.

(b) Appointments to advisory committees

(1) Recruitment

(A) In general

The Secretary shall—

(i) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

(ii) seek input from professional and medical and scientific societies to determine the most effective informational and recruitment activities; and

(iii) take into account the advisory committees with the greatest number of vacancies.

(B) Recruitment activities

The recruitment activities under subparagraph (A) may include—

(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

(ii) making widely available, including by using existing electronic communica-
(c) Disclosures; prohibitions on participation; waivers

(1) Disclosure of financial interest

Prior to a meeting of an advisory committee regarding a “particular matter” (as that term is used in section 208 of title 18), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

(2) Prohibitions and waivers on participation

(A) In general

Except as provided under subparagraph (B), a member of an advisory committee may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

(B) Waiver

If the Secretary determines it necessary to afford the advisory committee essential expertise, the Secretary may grant a waiver of the prohibition in subparagraph (A) to permit a member described in such subparagraph to—

(i) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

(ii) participate as a voting member with respect to a particular matter considered in a committee meeting.

(C) Limitation on waivers and other exceptions

(i) Definition

For purposes of this subparagraph, the term “exception” means each of the following with respect to members of advisory committees:

(I) A waiver under section 355(n)(4) of this title (as in effect on the day before September 27, 2007),

(II) A written determination under section 208(b) of title 18,

(III) A written certification under section 208(b)(3) of such title.

(ii) Determination of total number of members slots and member exceptions during fiscal year 2007

The Secretary shall determine—

(I)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who participated in the meeting; and

(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the “total number of 2007 meeting slots”);

(II)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who received an exception for the meeting; and

(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the “total number of 2007 meeting exceptions”).

(iii) Determination of percentage regarding exceptions during fiscal year 2007

The Secretary shall determine the percentage constituted by—

(I) the total number of 2007 meeting exceptions; divided by

(II) the total number of 2007 meeting slots.

(iv) Limitation for fiscal years 2008 through 2012

The number of exceptions at the Food and Drug Administration for members of advisory committees for a fiscal year may not exceed the following:

(I) For fiscal year 2008, 95 percent of the percentage determined under clause (iii) (referred to in this clause as the “base percentage”);

(II) For fiscal year 2009, 90 percent of the base percentage.

(III) For fiscal year 2010, 85 percent of the base percentage.

(IV) For fiscal year 2011, 80 percent of the base percentage.

(V) For fiscal year 2012, 75 percent of the base percentage.

(v) Allocation of exceptions

The exceptions authorized under clause (iv) for a fiscal year may be allocated within the centers or other organizational units of the Food and Drug Administration as determined appropriate by the Secretary.
(3) Disclosure of waiver

Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

(A) 15 or more days in advance

As soon as practicable, but (except as provided in subparagraph (B)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, a written certification as referred to in section 208(b)(3) of title 18, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5 and section 552a of title 5 (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet Web site of the Food and Drug Administration—

(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

(ii) the reasons of the Secretary for such determination, certification, or waiver.

(B) Less than 30 days in advance

In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, a written certification as referred to in section 208(b)(3) of title 18, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5 and section 552a of title 5) on the Internet Web site of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such disclosure, certification, or waiver, but in no case later than the date of such meeting.

(d) Public record

The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(3) (other than information exempted from disclosure under section 552 of title 5 and section 552a of title 5).

(e) Annual report

Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report that describes—

(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(3) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

(3) with respect to such year, the number of times the disclosures required under subsection (c)(3) occurred under subparagraph (B) of such subsection; and

(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

(f) Periodic review of guidance

Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.


REFERENCES IN TEXT


PRIOR PROVISIONS

A prior section 712 of act June 23, 1938, was renumbered section 711 by Pub. L. 102–571 and is classified to section 379d of this title.

EFFECTIVE DATE

Section effective Oct. 1, 2007, see section 701(c) of Pub. L. 110–85, set out as an Effective Date of 2007 Amendment note under section 355 of this title.

§379d-2. Policy on the review and clearance of scientific articles published by FDA employees

(a) Definition

In this section, the term “article” means a paper, poster, abstract, book, book chapter, or other published writing.

(b) Policies

The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.
(c) Timing of submission for review
If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is directed by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other office of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

(d) Timing for review and clearance
The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

(e) Non-timely review
If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

(f) Effect
Nothing in this section shall be construed as affecting any restrictions on such publication or presentation provided by other provisions of law.


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(a), 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 tolerances) 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(e) 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 in man or animal, 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 petition shall not 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 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 pre-
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, Government Organization and Efficiency, which enacted Title 5, Government Organization and Efficiency, and other terms, insofar as also used in the basic Act and other terms, insofar as also used in the basic Act, shall have the same meaning as they have, or had when in effect, under the basic Act.

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 such additive shall be 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 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 admitting to listing and certification of a significant period of time and authorizing the Secretary to make determinations as to listing of such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.


**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 703(d) of the Administrative Procedure Act (5 U.S.C., sec. 1003(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)”.


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.

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, Government Organization and Efficiency, which enacted Title 5, Government Organization and Efficiency, and other terms, insofar as also used in the basic Act, shall have the same meaning as they have, or had when in effect, under the basic Act.

“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, 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, 342, 346, 349, 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 of time, through provisional listings, the admission to listing and certification 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 amended, or repealed by the Secretary without regard to the requirements of the basic Act [subsection (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 paragraph (1)(E) of this subsection, or (B) 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, with the Secretary, specify with particularity the provisions 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, nor 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) that the 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 thereto 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 such publication, file 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. The 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(a) or (c) [now 721(b), (c)] of the basic Act [subsec. (b) or (c) of this section].

"(5) 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. 294. [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. 1250, 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 1, §161(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.
manufactured'' does not include packaging.

For purposes of this paragraph, the term products are manufactured in final dosage form.

``human drug applications'' means the following

at which one or more prescription drug prod-

injection for intravenous use or infusion.

(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,

(B) which may be dispensed only under prescription pursuant to section 355(b) of this title, and

(C) which is on the list of products described in section 355(j)(7)(A) of this title (not including the discontinued section of such list) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 262 of title 42 (not including the discontinued section of such list).

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 282 of title 42. Such term does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product that is licensed for further manufacturing use only, and does not include a bovine blood product for topical application licensed 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 substantial further manufacturing (such as capsules, tablets, or lyophilized products before reconstitution).

(5) The term ``prescription drug establishment'' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form. 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.

(F) Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 355(o) of this title (relating to postapproval studies and clinical trials and labeling changes) and section 355(p) of this title (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 355(k)(5) of this title (relating to adverse event reports and postmarket safety activities).

(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, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors,

(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 Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

(9) The term ``person'' includes an affiliate thereof.
(10) The term "active", with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.

Par. (11) "The term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.


AMENDMENT OF SECTION

For termination of amendment by section 106(a) of Pub. L. 110–85, see Effective and Termination Dates of 2007 Amendment note below.

For termination of amendment by section 509 of Pub. L. 107–188, see Effective and Termination Dates of 2002 Amendment note below.


TERMINATION OF SECTION

For termination of section by section 105 of Pub. L. 102–571, see Termination Date note below.

AMENDMENTS

2007—Par. (1)(B). Pub. L. 111–148 substituted "subsection (a) or (k) of section 262 of title 42" for "section 262 of title 42''.

2002—Par. (1). Pub. L. 107–188, §§503(1), 509, temporarily substituted "licensure, as described in subparagraph (C) for "licensure, as described in subparagraph (D)" in concluding provisions. See Effective and Termination Dates of 2002 Amendment note below.

Par. (3). Pub. L. 107–188, §§503(2)(D), 509, which directed the temporary amendment of concluding provisions of par. (3) by striking "section 262 of title 42'' and all that follows through "biological product'' and inserting "section 262 of title 42. Such term does not include a biological product'', was executed by striking language ending with "biological product'' the first time appearing, thereby making the substitution for "section 262 of title 42. does not include a large volume parenteral drug product approved before September 1, 1992. does not include a biological product'', to reflect the probable intent of Congress. See Effective and Termination Dates of 2002 Amendment note below.

Par. (4). Pub. L. 110–85, §§102(4), 106(a), temporarily inserted "(such as capsules, tablets, or lyophilized products before reconstitution)'' before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Par. (6)(F). Pub. L. 110–85, §§102(5), 106(a), temporarily amended par. (F) generally. Prior to amendment, par. (F) read as follows: "In the case of drugs approved after October 1, 2002, under human drug applications or supplements: collecting, developing, and reviewing safety information on the drugs, including adverse event reports, during a period of time after approval of such applications or supplements, not to exceed three years.''. See Effective and Termination Dates of 2007 Amendment note below.


Par. (9). Pub. L. 110–85, §§102(7), (8), 106(a), temporarily added pars. (9) and (10) and redesignated former par. (9) as (11). See Effective and Termination Dates of 2007 Amendment note below.


Par. (12). Pub. L. 107–188, §§503(4), 509, temporarily struck out designations of subpars. (A) and (B) and text of subpar. (B) and concluding provisions, substituting definition of "adjustment factor'' as the Consumer Price Index for definition of Index as the lower of the Consumer Price Index or the total of discretionary budget authority provided for programs in the domestic category for the immediately preceding fiscal year divided by such budget authority for fiscal year 1997. See Effective and Termination Dates of 2002 Amendment note below.

1997—Par. (1). Pub. L. 105–115, §§102(1), 107, in closing provisions, temporarily struck out "and'' before "does not include an application'' and substituted "September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume parenteral drug product approved before September 1, 1992 for intravenous use or infusion'' for "September 1, 1992'' before period at end. See Effective and Termination Dates of 1997 Amendment note below.

Par. (2). Pub. L. 105–115, §§125(b)(2)(M), inserted "or'' at end of subpar. (B), redesignated subpar. (D) as (C), and struck out former subpar. (C) which read as follows: "initial certification or initial approval of an antibiotic drug under section 577 of this title.''. See Effective and Termination Dates of 2007 Amendment note below.

Par. (3). Pub. L. 105–115, §§102(2), 107, in closing provisions, temporarily struck out "and'' before "does not
include a large volume parenteral drug'' and substituted “September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion” for “for ‘‘August 1992’’ before period at end. See Effective and Termination Dates of 1997 Amendment note below.


Par. (5). Pub. L. 105–115, §§102(4), 107, temporarily amended first sentence generally. Prior to amendment, first sentence read as follows: “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.”

See Effective and Termination Dates of 1997 Amendment note below.


Effective and Termination Dates of 2007 Amendment

Pub. L. 110–85, title I, §106(a), Sept. 27, 2007, 121 Stat. 842, provided that: “The amendments made by sections 102, 103, and 104 [enacting section 379h–1 of this title and amending this section and section 379h of this title] cease to be effective October 1, 2007.”

Pub. L. 110–85, title I, §107, Sept. 27, 2007, 121 Stat. 842, provided that: “The amendments made by sections 102 and 103 [amending this section and section 379h of this title] cease to be effective October 1, 2002, and section 104 [enacting provisions formerly set out as a note below] ceases to be effective 120 days after such date.”

Termination Date

Pub. L. 102–571, title I, §105, Oct. 29, 1992, 106 Stat. 4438, 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 formerly set out as a note below] shall not be in effect after 120 days after such date.”

Savings Provision

Pub. L. 110–85, title I, §110, Sept. 27, 2007, 121 Stat. 842, provided that: “Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note) [Pub. L. 107–188, and notwithstanding the amendments made by this title [enacting sections 379h–1 and 379h–2 of this title and amending this section and sections 379h and 379h–11 of this title], part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], as in effect on the day before the date of the enactment of this title [Sept. 27, 2007], shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.”


Effective and Termination Dates of 2002 Amendment


Pub. L. 107–188, title V, §509, June 12, 2002, 116 Stat. 694, provided that: “The amendments made by sections 503 and 504 [amending this section and section 379h of this title] cease to be effective October 1, 2007, and section 505 [enacting provisions set out as a note below] ceases to be effective 120 days after such date.”

Effective and Termination Dates of 1997 Amendment


Pub. L. 105–115, title I, §107, Nov. 21, 1997, 111 Stat. 2395, provided that: “The amendments made by sections 102 and 103 [amending this section and section 379h of this title] cease to be effective October 1, 2002, and section 104 [enacting provisions formerly set out as a note below] ceases to be effective 120 days after such date.”

Effective and Termination Dates of 2007 Amendment

Pub. L. 110–85, title I, §§106(a), Sept. 27, 2007, 121 Stat. 842, provided that: “Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g) [Pub. L. 107–188, and notwithstanding the amendments made by this title [enacting sections 379h–1 and 379h–2 of this title and amending this section and sections 379h and 379h–11 of this title], part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], as in effect on the day before the date of the enactment of this title [Sept. 27, 2007], shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.”

Pub. L. 107–188, title V, §507, June 12, 2002, 116 Stat. 694, provided that: “Notwithstanding section 107 of the Food and Drug Administration Modernization Act of 1997 [section 107 of Pub. L. 106–115, set out as an Effective and Termination Dates of 1997 Amendment note above], and notwithstanding the amendments made by this subtitle [subtitle A (§§501–509) of title V of Pub. L. 107–188, amending this section and sections 379h and 379h–11 of this title] shall take effect October 1, 2007, or the date of the enactment of this Act [Sept. 27, 2007], whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], as in effect on the day before the date of the enactment of this Act [June 12, 2002], continues to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that, on or after October 1, 1997, but before October 1, 2002, were accepted by the Food and Drug Administration for filing and with respect to assessing and collecting any fee required by such Act for a fiscal year prior to fiscal year 2003.”


Accountability and Reports

Services to consult with various congressional committees and health care professionals and provide for public commentary when developing recommendations to Congress regarding review of human drug applications for fiscal years after 2007, and which required the Secretary to submit performance and fiscal reports on certain goals and fees beginning with fiscal year 2003, ceased to be effective 120 days after Oct. 1, 2007. See Effective and Termination Dates of 2002 Amendment note above.

CONGRESSIONAL FINDINGS CONCERNING FEES RELATING TO DRUGS

Pub. L. 110–85, title I, §101(c), Sept. 27, 2007, 121 Stat. 825, provided that: “The Congress finds that the fees authorized by the amendments made in this title (enacting sections 379h–1 and 379h–2 of this title and amending this section and sections 379h and 379–11 of this title) will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (this subpart), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.


(1) prompt approval of safe and effective new drugs and other therapies 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 the review of human drug applications and the assurance of drug safety;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 [see section 101(a) of Pub. L. 102–571, set out as a Short Title of 1992 Amendment note under section 301 of this title] have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this subtitle [subtitle A (§§101–107) of title I of Pub. L. 105–115, amending this section and section 379h of this title] will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (this subpart), in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate, as set forth in the Congressional Record.


(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 Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources Committee of the Senate, as set forth at 138 Cong. Rec. H9099–H9100 (daily ed. September 22, 1992).”

ANNUAL REPORTS

Pub. L. 105–115, title I, §104, Nov. 21, 1997, 111 Stat. 2904, which directed the Secretary of Health and Human Services to prepare and submit to Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, within 60 days after the end of each fiscal year during which fees are collected under this subpart, a report stating the Food and Drug Administration’s progress in achieving the goals identified in the letters described in section 101(4) of Pub. L. 102–571, set out above, during such fiscal year and the Administration’s future plans for meeting the goals, and within 120 days after the end.
of each fiscal year during which fees are collected, to prepare and submit a report on the implementation of the authority for such fees during such fiscal year and on the use the Administration made of the fees collected during such fiscal year, ceased to be effective 120 days after Oct. 1, 2002. See section 107 of Pub. L. 105–115, set out as an Effective and Termination Dates of 1997 Amendment note above.

Pub. L. 102–571, title I, §104, Oct. 29, 1992, 106 Stat. 4498, which provided that the Secretary of Health and Human Services submit to Committee on Energy and Commerce of the House of Representatives and Committee on Labor and Human Resources of the Senate, within 60 days after the end of each fiscal year during which fees were collected under this subpart, a report stating the Food and Drug Administration’s progress in achieving the goals identified in section 102(3) of Pub. L. 102–571, set out as a note above, during such fiscal year and on the use the Food and Drug Administration made of the fees collected during such fiscal year, ceased to be in effect 120 days after Oct. 1, 1997. See Termination Date note above.

ANIMAL DRUG USER FEE STUDY

Pub. L. 102–571, title I, §108, Oct. 29, 1992, 106 Stat. 4500, directed Secretary, in consultation with manufacturers of animal drug products and other interested persons, to undertake study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds in order to improve process of reviewing applications (including abbreviated and supplemental applications) for new animal drugs under section 360b of this title, and further provided for submission of study to Congress no later than Jan. 4, 1994.

§379h. Authority to assess and use drug fees

(a) Types of fees

Beginning in fiscal year 2008, 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 under subsection (c)(5) 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 under subsection (c)(5) 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. Such fee shall be half of the amount of the fee established under clause (i).

(B) Payment

The fee required by subparagraph (A) shall be due upon submission of the application or supplement.

(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 refused for filing or withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

(E) Fees for applications previously refused for filing or withdrawn before filing

A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (B) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

(F) Exception for designated orphan drug or indication

A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 360bb of this title shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 360bb of this title as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

(G) Refund of fee if application withdrawn

If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) Prescription drug establishment fee

(A) In general

Except as provided in subparagraphs (B) and (C), each person that—

(i) is named as the applicant in a human drug application; and

(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement,
shall be assessed an annual fee established under subsection (c)(5) of this section for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before October 1 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

(B) Exception

If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

(i) that did not manufacture the product in the previous fiscal year; and

(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.

(C) Special rules for positron emission tomography drugs

(i) In general

Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a positron emission tomography drug shall be subject under subparagraph (A) to one-sixth of an annual establishment fee with respect to each such establishment identified in the application as producing positron emission tomography drugs under the approved application.

(ii) Exception from annual establishment fee

Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

(I) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and

(II) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

(iii) Definition

For purposes of this subparagraph, the term “positron emission tomography drug” has the meaning given to the term “compounded positron emission tomography drug” in section 321(ii) of this title, except that paragraph (1)(B) of such section shall not apply.

(3) Prescription drug product fee

(A) In general

Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and 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 under subsection (c)(5) of this section. Such fee shall be payable on or before October 1 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

(B) Exception

A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 355(j)(7)(A) of this title with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 355(b) or 355(j) of this title, under an abbreviated application filed under section 357 of this title (as in effect on the day before November 21, 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

(b) Fee revenue amounts

(1) In general

For each of the fiscal years 2008 through 2012, fees under subsection (a), except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

(A) $392,783,000; and

(B) an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).

(2) Types of fees

Of the total revenue amount determined for a fiscal year under paragraph (1)—

(A) one-third shall be derived from fees under subsection (a)(1) (relating to human drug applications and supplements);

(B) one-third shall be derived from fees under subsection (a)(2) (relating to prescription drug establishments); and

(C) one-third shall be derived from fees under subsection (a)(3) (relating to prescription drug products).
(3) Modified workload adjustment factor for fiscal year 2007

For purposes of paragraph (1)(B), the Secretary shall determine the modified workload adjustment factor by determining the dollar amount that results from applying the methodology that was in effect under subsection (c)(2) for fiscal year 2007 to the amount $354,893,000, except that, with respect to the portion of such determination that is based on the change in the total number of commercial investigational new drug applications, the Secretary shall count the number of such applications that were active during the most recent 12-month period for which data on such submissions is available.

(4) Additional fee revenues for drug safety

(A) In general

For each of the fiscal years 2008 through 2012, paragraph (1)(A) shall be applied by substituting the amount determined under subparagraph (B) for "$392,783,000".

(B) Amount determined

For each of the fiscal years 2008 through 2012, the amount determined under this subparagraph is the sum of—

(i) $392,783,000; plus

(ii) (I) for fiscal year 2008, $25,000,000; (II) for fiscal year 2009, $35,000,000; (III) for fiscal year 2010, $45,000,000; (IV) for fiscal year 2011, $55,000,000; and (V) for fiscal year 2012, $65,000,000.

(c) Adjustments

(1) Inflation adjustment

For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12 month period ending June 30 preceding the fiscal year for which fees are being established.

(B) the total percentage change for the previous 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, or

(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

(2) Workload adjustment

For fiscal year 2009 and subsequent fiscal years, after the fee revenues established in subsection (b) of this section are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for the fiscal year established in subsection (b) of this section, as adjusted for inflation under paragraph (1). Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities.

(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees and revenue amounts for fiscal year 2009 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of the fiscal years 2010 through 2012. The Secretary shall not make any adjustment for changes in review activities for any fiscal year after 2009 unless such study has been completed.

(3) Rent and rent-related cost adjustment

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established in subsection (b) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2006. Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the estimates made in fiscal year 2006 for such fiscal year, and shall not exceed $11,721,000 for any fiscal year.
§ 379h  TITLE 21—FOOD AND DRUGS  Page 336

(4) Final year adjustment
(A) Increase in fees
For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2013. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2012. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

(B) Decrease in fees
(i) In general
For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), decrease the fee revenues and fees established in subsection (b) by the amount determined in clause (ii), if, for fiscal year 2009 or 2010—
(I) the amount of the total appropriations for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriations for the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1); and
(II) the amount of the total appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1).

(ii) Amount of decrease
The amount determined in this clause is the lesser of—
(I) the amount equal to the sum of the amounts that, for each of fiscal years 2009 and 2010, is the lesser of—
(aa) the excess amount described in clause (i)(II) for such fiscal year; or
(bb) the amount specified in subsection (b)(4)(B)(i) for such fiscal year; or
(II) $65,000,000.

(iii) Limitations
(I) Fiscal year condition
In making the determination under clause (ii), an amount described in subclause (I) of such clause for fiscal year 2009 or 2010 shall be taken into account only if subclauses (I) and (II) of clause (i) apply to such fiscal year.

(II) Relation to subparagraph (A)
The Secretary shall limit any decrease under this paragraph if such a limitation is necessary to provide for the 3 months of operating reserves described in subparagraph (A).

(5) Annual fee setting
The Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2007, establish, for the next fiscal year, application, product, and establishment fees under subsection (a) of this section, based on the revenue amounts established under subsection (b) of this section and the adjustments provided under this subsection.

(6) Limit
The total amount of fees charged, as adjusted under this subsection, 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
(1) In general
The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) of this section where the Secretary finds that—
(A) such waiver or reduction is necessary to protect the public health,
(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,
(C) 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
(D) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

(2) Considerations
In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) Use of standard costs
In making the finding in paragraph (1)(C), the Secretary may use standard costs.

(4) Rules relating to small businesses
(A) “Small business” defined
In paragraph (1)(D), the term “small business” means an entity that has fewer than 500 employees, including employees of affiliates, that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce.

(B) Waiver of application fee
The Secretary shall waive under paragraph (1)(D) the application fee for the first human
drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

(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) Limitations

(1) In general

Fees under subsection (a) of this section shall be refunded for a fiscal year beginning after fiscal year 1997 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 1997 (excluding the amount of fees appropriated for such fiscal year) 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 authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) Collections and appropriation acts

(A) In general

The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) 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, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

(B) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (A)(i) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(II) such costs are not more than 5 percent below the level specified in such subparagraph.

(3) Authorization of appropriations

For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4) of this section.

(4) Offset

If the sum of the cumulative amount of fees collected under this section for the fiscal years 2008 through 2010 and the amount of fees estimated to be collected under this section for fiscal year 2011 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2008 through 2011, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.

(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) Written requests for waivers, reductions, and refunds
To qualify for consideration for a waiver or reduction under subsection (d) of this section, or for a refund of any fee collected in accordance with subsection (a) of this section, a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) 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, employes, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employes, and advisory committees so engaged.

(k) Orphan drugs
(1) Exemption
A drug designated under section 360b of this title for a rare disease or condition and approved under section 355 of this title or section 262 of title 42 shall be exempt from product and establishment fees under this section, if the drug meets all of the following conditions:

(A) The drug meets the public health requirements contained in this chapter as such requirements are applied to requests for waivers for product and establishment fees.

(B) The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue during the most recent 12-month period before the exemption was requested.


(2) Evidence of qualification
An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed $50,000,000 for the preceding 12 months before the exemption was requested.


Subsec. (a)(1)(D). Pub. L. 110–85, §§ 103(a)(2)(A), 106(a), temporarily inserted “or withdrawn before filing” after “refused for filing” in heading and “or withdrawn without a waiver before filing” before period at end of text. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(1)(E) to (G). Pub. L. 110–85, §§ 103(a)(2)(B), (C), 106(a), temporarily added subpar. (E) and redesignated former subpars. (E) and (F) as (F) and (G), respectively. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A). Pub. L. 110–85, §§ 103(a)(3)(A), (g), 106(a), temporarily substituted subparagraphs (B) and (C) for “subparagraph (B)” in concluding provisions. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(C). Pub. L. 110–85, §§ 103(a)(3)(B), 106(a), temporarily added subpar. (C) and redesignated former subpar. (C) as (D). See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (b). Pub. L. 110–85, §§ 103(b), 106(a), temporarily amended subsec. (b) generally, substituting provisions contained in pars. (1) to (4) relating to fee revenue amounts for fiscal years 2008 through 2012 for undesignated provisions relating to fee schedules for fiscal years 2003 to 2007. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(1). Pub. L. 110–85, §§ 103(c)(1), 106(a), temporarily amended par. (1) by substituting “For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b)” for “The revenues established in subsection (b)” in introductory provisions, adding subpar. (C), and substituting “fiscal year 2008” for “fiscal year 2003” in concluding provisions. See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (c)(2)(A). Pub. L. 110–85, §§ 103(c)(2)(B), 106(a), temporarily substituted “human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary,” for “human drug applications, commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available,” for “human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary,” in first sentence. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2)(B). Pub. L. 110–85, §§ 103(c)(2)(C), 106(a), temporarily inserted at end “Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 per-
percent points higher than it would have been in the absence of the adjustment for changes in review activities.” See Effective and Termination Dates of 2007 Amendment note below.


Effective and Termination Dates of 2007 Amendment note below.


Subsec. (e)(1). Pub. L. 110–85, §§106(c)(1), 106(a), temporarily added par. (1) and redesignated former par. (2) as (3). Former par. (3) redesignated (4). See Effective and Termination Dates of 2007 Amendment note below.

Effective and Termination Dates of 2007 Amendment note below.

Subsec. (f)(1). Pub. L. 110–85, §§106(c)(2), 106(a), temporarily added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4). See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (g)(1). Pub. L. 110–85, §§106(h)(1), 106(a), temporarily substituted “’ Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.” for “’ 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 2003 to 2007.” See Effective and Termination Dates of 2007 Amendment note below.

Effective and Termination Dates of 2007 Amendment note below.


Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(4). Pub. L. 110–85, §§106(e)(2), 106(a), temporarily reenacted heading without change and amended text generally. Prior to amendment, text read as follows: “Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section, for the fiscal year.” See Effective and Termination Dates of 2007 Amendment note below.

Effective and Termination Dates of 2007 Amendment note below.


Subsec. (a)(1)(A)(i). Pub. L. 107–188, §§504(a)(2), 509, temporarily substituted “under subsection (c)(4)” for “in subsection (b)” and inserted “Such fee shall be half of the amount of the fee established under clause (i)’” at end. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (a)(1)(F). Pub. L. 107–109 redesignated subpar. (G) as (F) and struck out heading and text of former subpar. (F). Text read as follows: “’A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).’”


Subsec. (a)(3)(A). Pub. L. 107–188, §§504(a)(4)(A), 509, temporarily amended heading and text of subpar. (A) generally. Prior to amendment, text read as follows: “’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 has been submitted for listing 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 for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for re-listing under section 360 of this title if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.'” See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (a)(3)(B). Pub. L. 107–188, §§504(a)(4)(B), 509, temporarily substituted “A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is the same product as a product approved under an application filed under section 355(b) of this title, and is submitted for listing under section 360 of this title.” See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (b). Pub. L. 107–188, §§504(b), 509, temporarily amended heading and text of subsec. (b) generally, subtituting “’Fee revenue amounts’” for “’Fee amounts’” in


Subsec. (c)(1)(B). Pub. L. 107–188, §§ 504(c)(1)(B), 509, temporarily struck out "during the preceding fiscal year" before "in the Consumer Price Index" and substituted "for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, renewed, or" for ", or". See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (c)(2) to (5). Pub. L. 107–188, §§ 504(c)(2)–(4), 509, temporarily added paras. (2) and (3), redesignated former paras. (2) and (3) as (4) and (5), respectively, and amended heading and text of par. (4) generally. Prior to amendment, text read as follows: "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 September 30, 1997, adjust the establishment and product fees described in subsection (b) of this section for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) of this section shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b) of this section." See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (c)(1)(C) to (E). Pub. L. 107–188, §§ 504(d)(1), 509, temporarily added paras. (2) and (3), redesignated former subpar. (E) as (D), and struck out former subpar. (D) which read as follows: "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, or", See Effective and Termination Dates of 2002 Amendment note below.


Subsec. (c)(2). Pub. L. 107–188, §§ 504(e)(2), 509, temporarily substituted "in general" for "limitation" in heading and "fees under subsection (a) of this section shall be refunded for a fiscal year beginning" for "fees may not be assessed under subsection (a) of this section for a fiscal year beginning" in text. See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (c)(1)(F). Pub. L. 107–188, §§ 504(f)(1), 509, which directed the temporary amendment of par. (1) by striking "fees collected for a fiscal year" and all that follows through "fiscal year limitation." and inserting "fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended", was not executed because the phrase "fiscal year limitation." appeared in two places and because of the corrective amendment by Pub. L. 110–85, § 355(b)(1), which is effective as if included in Pub. L. 107–188, § 504. See Effective and Termination Dates of 2002 Amendment note and Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(2). Pub. L. 107–188, §§ 504(f)(2), 509, temporarily amended par. (2) by designating existing provisions as subpar. (A), inserting subpar. (A) heading, adding subpar. (B), redesignating former subpars. (A) and (B) as cls. (i) and (ii), respectively, of subpar. (A), substituting "shall be retained in each fiscal year in an amount not to exceed the amount specified" for "shall be collected for each fiscal year under this section to the amount specified" in cl. (i), and realigning margin of cl. (ii). See Effective and Termination Dates of 2002 Amendment note below.

Subsec. (g)(3)(A) to (E). Pub. L. 107–188, §§ 504(f)(3), 509, temporarily added subpars. (A) to (E) and struck out former subpars. (A) to (E) which read as follows: 

"(A) $106,800,000 for fiscal year 1998; 

"(B) $109,200,000 for fiscal year 1999; 

"(C) $109,200,000 for fiscal year 2000; 

"(D) $114,000,000 for fiscal year 2001; and 

"(E) $116,100,000 for fiscal year 2002.

See Effective and Termination Dates of 2002 Amendment note below.


Subsec. (a)(1)(B). Pub. L. 105–115, §§ 103(a)(2)(A), 107, temporarily amended heading and text of subpar. (B) generally. Prior to amendment, text read as follows: 

	(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—

	(1) 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(b) of this title; or 

	(2) 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." See Effective and Termination Dates of 1997 Amendment note below.


Subsec. (a)(2). Pub. L. 105–115, §§ 103(a)(2), 107, temporarily reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "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(i) 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." See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (a)(3)(A). Pub. L. 105–115, §§ 103(a)(3)(A), 107, temporarily substituted, in cl. (i), "has been submitted for listing", in cl. (ii), "has been submitted for listing", and, in closing provisions, Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the product has been withdrawn

Subsec. (g)(3)(A). Pub. L. 105–115, §§ 103(a)(3)(A), 107, temporarily substituted, in cl. (i), "has been submitted for listing" for "is listed" and, in closing provisions, Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the product has been withdrawn
from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable. For “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 for each prescription drug product irrespective of the number of times such product is listed under section 360 of this title.” See Effective and Termination Dates of 1997 Amendment note below.


Subsec. (b). Pub. L. 105–115, §§103(b), 107, temporarily amended subsec. (b) generally. Prior to amendment, subsec. (b) related to fee amounts, including a schedule of fees in par. (1) and fee exceptions for certain small businesses in par. (2). See Effective and Termination Dates of 1997 Amendment note below.


Subsec. (c)(1). Pub. L. 105–115, §§103(c)(2), 107, temporarily substituted “Inflation adjustment” for “Revenue increase” in heading. “The fees and total fee revenues established in subsection (b) of this section shall be decreased by the Secretary” for “The total fee revenues established by the schedule in subsection (b)(1) of this section shall be increased by the Secretary” in introductory provisions, and “and change” for “increase” after “total percentage” in subpars. (A) and (B), and inserted at end “The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.” See Effective and Termination Dates of 1997 Amendment note below.

Subsec. (c)(2). Pub. L. 105–115, §§103(c)(3), 107, temporarily substituted “September 30, 1997, adjust the establishment and product fees described in subsection (b) of this section for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) of this section shall be set to be equal to the revenues collected from the category of fee in effect prior to the application and supplement fees described in paragraph (1) of subsection (b) of this section.” for “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.” See Effective and Termination Dates of 1997 Amendment note below.


Subsec. (d). Pub. L. 105–115, §§103(d), 107, temporarily struck out introductory provisions which read “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—” and closing provisions which read “In making the finding in paragraph (3), the Secretary may use standard costs.”, inserted designation, heading, and introductory provisions of par. (1), redesignated former paras. (1) to (4) as subpars. (A) to (D), respectively, of par. (1), and added paras. (1)(E), (2), and (3). See Effective and Termination Dates of 1997 Amendment note below.


Subsec. (g)(1). Pub. L. 105–115, §§103(f)(1), 107, temporarily inserted at end “Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available only for the process for the review of human drug applications.” See Effective and Termination Dates of 1997 Amendment note below.


Subsec. (g)(3), (4). Pub. L. 105–115, §§103(f)(3), 107, temporarily added pars. (3) and (4) and struck out heading and text of former par. (3). Text read as follows: “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,

(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.” See Effective and Termination Dates of 1997 Amendment note below.


EFFECTIVE AND TERMINATION DATES OF 2007

Amendment by Pub. L. 110–85, title I, §379h(2), Sept. 27, 2007, 121 Stat. 832, provided that: “Paragraph (1) [amending this section] shall take effect as if included in section 304 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188; 116 Stat. 687) [amending this section].”

Amendment by Pub. L. 110–85 to cease to be effective Oct. 1, 2012, see section 106(a) of Pub. L. 110–85, set out as a note under section 379g of this title.

Amendment by Pub. L. 110–85 effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, see section 107 of Pub. L. 110–85, set out as a note under section 379g of this title.

EFFECTIVE AND TERMINATION DATES OF 2002


EFFECTIVE AND TERMINATION DATES OF 1997


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.
SPECIAL RULE FOR WAIVERS AND REFUNDS

Section 103(h) of Pub. L. 105–115 provided that: “Any requests for waivers or refunds for fees assessed under section 736 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 379h) prior to the date of enactment of this Act (Nov. 21, 1997) shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act. Any requests for waivers or refunds pertaining to a fee for a human drug application or supplement accepted for filing prior to October 1, 1997 or to a product or establishment fee required by such Act for a fiscal year prior to October 1, 1996, shall be evaluated according to the terms of the Prescription Drug User Fee Act of 1992 [see section 101(a) of Pub. L. 102–571, set out as a Short Title of 1992 Amendment note under section 301 of this title] (as in effect on September 30, 1997) and part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379g et seq.] (as in effect on September 30, 1997). The term ‘person’ in such Acts shall continue to include an affiliate thereof.”

§ 379h–1. Fees relating to advisory review of prescription-drug television advertising

(a) Types of direct-to-consumer television advertisement review fees

Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Advisory review fee

(A) In general

With respect to a proposed direct-to-consumer television advertisement (referred to in this section as a “DTC advertisement”), each person that on or after October 1, 2007, submits such an advertisement for advisory review by the Secretary prior to its initial public dissemination shall, except as provided in subparagraph (B), be subject to a fee established under subsection (c)(3).

(B) Exception for required submissions

A DTC advertisement that is required to be submitted to the Secretary prior to initial public dissemination is not subject to a fee under subparagraph (A) unless the sponsor designates the submission as a submission for advisory review.

(C) Notice to Secretary of number of advertisements

Not later than June 1 of each fiscal year, the Secretary shall publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of DTC advertisements the person intends to submit for advisory review in the next fiscal year. Notwithstanding the preceding sentence, for fiscal year 2008, the Secretary shall publish such a notice in the Federal Register not later than 30 days after September 27, 2007.

(D) Payment

(i) In general

The fee required by subparagraph (A) (referred to in this section as “an advisory review fee”) shall be due not later than October 1 of the fiscal year in which the DTC advertisement involved is intended to be submitted for advisory review, subject to subparagraph (F)(i). Notwithstanding the preceding sentence, the advisory review fee for any DTC advertisement that is intended to be submitted for advisory review during fiscal year 2008 shall be due not later than 120 days after September 27, 2007, or an earlier date as specified by the Secretary.

(ii) Effect of submission

Notification of the Secretary under subparagraph (C) of the number of DTC advertisements a person intends to submit for advisory review is a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. Notwithstanding the preceding sentence, the commitment shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions for fiscal year 2008 by the date specified in clause (i).

(iii) Notice regarding carryover submissions

In making a notification under subparagraph (C), the person involved shall in addition notify the Secretary if under subparagraph (F)(i) the person intends to submit a DTC advertisement for which the advisory review fee has already been paid. If the person does not so notify the Secretary, each DTC advertisement submitted by the person for advisory review in the fiscal year involved shall be subject to the advisory review fee.

(E) Modification of advisory review fee

(i) Late payment

If a person has submitted a notification under subparagraph (C) with respect to a fiscal year and has not paid all advisory review fees due under subparagraph (D) not later than November 1 of such fiscal year (or, in the case of such a notification submitted with respect to fiscal year 2008, not later than 150 days after September 27, 2007, or an earlier date specified by the Secretary), the fees shall be regarded as late and an increase in the amount of fees applies in accordance with this clause, notwithstanding any other provision of this section. For such person, all advisory review fees for such fiscal year shall be due and payable 20 days before any direct-to-consumer advertisement is submitted to the Secretary for advisory review, and each such fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

(ii) Exceeding identified number of submissions

If a person submits a number of DTC advertisements for advisory review in a fiscal year that exceeds the number identified by the person under subparagraph (C), an increase in the amount of fees applies under this clause for each submission in excess of such number, notwithstanding
any other provision of this section. For each such DTC advertisement, the advisory review fee shall be due and payable 20 days before the advertisement is submitted to the Secretary, and the fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

(F) Limits
   (i) Submissions
   For each advisory review fee paid by a person for a fiscal year, the person is entitled to acceptance for advisory review by the Secretary of one DTC advertisement and acceptance of one resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over not more than one paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

(ii) No refunds
   Except as provided by subsections (d)(4) and (f), fees paid under this section shall not be refunded.

(iii) No waivers, exemptions, or reductions
   The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

(iv) Right to advisory review not transferable
   The right to an advisory review under this paragraph is not transferable, except to a successor in interest.

(2) Operating reserve fee
   (A) In general
   Each person that on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to fee

1 established under subsection (d)(2) (referred to in this section as an “operating reserve fee”) for the first fiscal year in which an advisory review fee is assessed to such person. The person is not subject to an operating reserve fee for any other fiscal year.

(B) Payment
   Except as provided in subparagraph (C), the operating reserve fee shall be due no later than—
   (i) October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1); or
   (ii) for fiscal year 2006, 120 days after September 27, 2007, or an earlier date specified by the Secretary.

(C) Late notice of submission
   If, in the first fiscal year of a person’s participation in the program under this section, that person submits any DTC advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (a)(1)(C), that person shall pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(E)(ii). Fees required by this subparagraph shall be in addition to any fees required by subparagraph (A). Fees under this subparagraph shall be due 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

(D) Late payment
   (i) In general
   Notwithstanding subparagraph (B), and subject to clause (ii), an operating reserve fee shall be regarded as late if the person required to pay the fee has not paid the complete operating reserve fee by—
   (I) for fiscal year 2008, 150 days after September 27, 2007, or an earlier date specified by the Secretary; or
   (II) in any subsequent year, November 1.

   (ii) Complete payment
   The complete operating reserve fee shall be due and payable 20 days before any DTC advertisement is submitted to the Secretary for advisory review.

(iii) Amount
   Notwithstanding any other provision of this section, an operating reserve fee that is regarded as late under this subparagraph shall be equal to 150 percent of the operating reserve fee that otherwise would have applied pursuant to subsection (d).

(b) Advisory review fee revenue amounts
   Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsections (c) and (g)(4).

(c) Adjustments
   (1) Inflation adjustment
   Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—
   (A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;
   (B) the total percentage change for the previous 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; or
   (C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 fiscal years of the previous 6 fiscal years.

1 So in original. Probably should be “the fee”.

\[\text{Page 343} \hspace{1cm} \text{TITLE 21—FOOD AND DRUGS} \hspace{1cm} \S 379b-1\]
§ 379h–1

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

(2) Workload adjustment

Beginning with fiscal year 2009, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of DTC advertisements for advisory review prior to initial dissemination. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based upon the number of DTC advertisements identified pursuant to subsection (a)(1)(C) for the upcoming fiscal year, excluding allowable previously paid carry over submissions. The adjustment shall be determined by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by $27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

(3) Annual fee setting for advisory review

(A) In general

Not later than August 1 of each fiscal year (or, with respect to fiscal year 2008, not later than 90 days after September 27, 2007), the Secretary shall establish for the next fiscal year the DTC advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under paragraphs (1) and (2), and the number of DTC advertisements identified pursuant to subsection (a)(1)(C), excluding allowable previously-paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of DTC advertisements so identified, excluding allowable previously-paid carry over submissions under subsection (a)(1)(F)(i).

(B) Fiscal year 2008 fee limit

Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for fiscal year 2008 may not be more than $383,000 per submission for advisory review.

(C) Annual fee limit

Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

(D) Limit

The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

(d) Operating reserves

(1) In general

The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least $6,250,000 in fiscal year 2008, to continue the program under this section in the event the fees collected in any subsequent fiscal year pursuant to subsection (a)(1) do not generate the fee revenue amount established for that fiscal year.

(2) Fee setting

The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee by multiplying the number of DTC advertisements identified by that person pursuant to subsection (a)(1)(C) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year, except that in no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the program under this section in fiscal year 2008.

(3) Use of operating reserve

The Secretary may use funds from the reserves only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsections (b) and (c) and the amount of fees actually collected for that fiscal year pursuant to subsection (a)(1), or to pay costs of ending the program under this section if it is terminated pursuant to subsection (f) or not reauthorized beyond fiscal year 2012.

(4) Refund of operating reserves

Within 120 days after the end of fiscal year 2012, or if the program under this section ends early pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the program under this section, shall refund all amounts remaining in the operating reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2).

(e) Effect of failure to pay fees

Notwithstanding any other requirement, a submission for advisory review of a DTC advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.
(f) Effect of inadequate funding of program

(1) Initial funding

If on November 1, 2007, or 120 days after September 27, 2007, whichever is later, the Secretary has not received at least $11,250,000 in advisory review fees and operating reserve fees combined, the program under this section shall not commence and all collected fees shall be refunded.

(2) Later fiscal years

Beginning in fiscal year 2009, if, on November 1 of the fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years falls below $9,000,000, adjusted for inflation (as described in subsection (c)(1)), the program under this section shall terminate, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and finally, unused advisory review fees from the relevant fiscal year.

(g) Crediting and availability of fees

(1) In general

Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

(2) Collections and appropriation acts

(A) In general

The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

(ii) shall be available for obligation only if the amounts appropriated as budget authority for such fiscal year are sufficient to support a number of full-time equivalent review employees that is not fewer than the number of such employees supported in fiscal year 2007.

(B) Review employees

For purposes of subparagraph (A)(ii), the term “full-time equivalent review employees” means the total combined number of full-time equivalent employees in—

(i) the Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration; and

(ii) the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, Food and Drug Administration.

(3) Authorization of appropriations

For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted pursuant to subsection (c) and paragraph (4) of this subsection, plus amounts collected for the reserve fund under subsection (d).

(4) Offset

Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

(h) Definitions

For purposes of this section:

(1) The term “advisory review” means reviewing and providing advisory comments on DTC advertisements regarding compliance of a proposed advertisement with the requirements of this chapter prior to its initial public dissemination.

(2) The term “advisory review fee” has the meaning indicated for such term in subsection (a)(1)(A).

(3) The term “carry over submission” means a submission for an advisory review for which a fee was paid in one fiscal year that is submitted for review in the following fiscal year.

(4) The term “direct-to-consumer television advertisement” means an advertisement for a prescription drug product (as defined in section 379g(3) of this title) intended to be displayed on any television channel for less than 3 minutes.

(5) The term “DTC advertisement” has the meaning indicated for such term in subsection (a)(1)(A).

(6) The term “operating reserve fee” has the meaning indicated for such term in subsection (a)(2)(A).

(7) The term “person” includes an individual, partnership, corporation, and association, and any affiliate thereof or successor in interest.

(8) The term “process for the advisory review of prescription drug advertising” means the activities necessary to review and provide advisory comments on DTC advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the program under this section that are not necessary for the advisory review of DTC advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

(9) The term “resources allocated for the process for the advisory review of prescription drug advertising” means the total combined number of full-time equivalent review employees that is not fewer than the number of such employees supported in fiscal year 2007.
drug advertising’’ means the expenses incurred in connection with the process for the advisory review of prescription drug advertising for—

(A) officers and employees of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

(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;

(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

(E) terminating the program under this section pursuant to subsection (f)(2) if that becomes necessary.

(10) The term ‘‘resubmission’’ means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary’s comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

(11) The term ‘‘submission for advisory review’’ means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.


§379h–2. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(b) Fiscal report

Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

§379h–2. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(b) Fiscal report

Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) Prior public input

Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and

(D) publish the comments on the Food and Drug Administration’s Internet Web site.

(3) Periodic consultation

Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).
Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

Transmittal of recommendations

Not later than January 15, 2012, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

Minutes of negotiation meetings

(A) Public availability

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) Content

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.


Termination of section

For termination of section by section 106(b) of Pub.L.110–85, see Effective and Termination Dates note below.

References in text

Section 101(c) of the Food and Drug Administration Amendments Act of 2007, referred to in subsec. (a), is section 101(c) of Pub.L.110–85, which is set out as a note under section 379f of this title.

Effective and termination dates


Section effective Oct.1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct.1, 2007, see section 107 of Pub.L.110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379f of this title.

Subpart 3—fees relating to devices

Termination of subpart

For termination of subpart by section 107 of Pub.L.107–250, see Effective and Termination Dates note set out under section 379i of this title.

§379i. Definitions

For purposes of this subpart:

(1) The term “premarket application” means—

(A) an application for approval of a device submitted under section 360e(c) of this title or section 262 of title 42; or

(B) a product development protocol described in section 366e(f) of this title.

Such term does not include a supplement, a premarket report, or a premarket notification submission.

(2) The term “premarket report” means a report submitted under section 360e(c)(2) of this title.

(3) The term “premarket notification submission” means a report submitted under section 360(k) of this title.

(A) The term “supplement”, with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

(i) an application or report has been approved under section 360e(d) of this title, or

(ii) an application has been approved under section 262 of title 42; or

(iii) a notice of completion has become effective under section 360e(f) of this title.

(B) The term “panel-track supplement”, means a supplement to an approved premarket application or premarket report under section 360e of this title that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term “180-day supplement” means a supplement to an approved premarket application or premarket report under section 360e of this title that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

(D) The term “real-time supplement” means a supplement to an approved premarket application or premarket report under section 360e of this title that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) The term “efficacy supplement” means a supplement to an approved premarket application under section 262 of title 42 that requires substantive clinical data.

(5) The term “30–day notice” means a notice under section 360e(d)(6) of this title that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

(6) The term “request for classification information” means a request made under sec-
§ 379i

(7) The term “annual fee”, for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.

(8) The term “process for the review of device applications” means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary’s review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

(E) Review of device applications subject to section 262 of title 42 for an investigational new drug application under section 355(i) of this title or for an investigational device exemption under section 360(j)(g) of this title and activities conducted in anticipation of the submission of such applications under section 355(i) or 360(j)(g) of this title.

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 360d of this title in connection with the review of such applications, reports, supplements, or submissions and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

(I) Any activity undertaken under section 360e or 360e(a) of this title in connection with the initial classification or recategorization of a device or under section 360e(b) of this title in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 360e of this title or a premarket application under section 262 of title 42.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

(9) The term “costs of resources allocated for the process for the review of device applications” means the expenses incurred in connection with the process for the review of device applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

(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 and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

(10) The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2001.

(11) The term “person” includes an affiliate thereof.

(12) The term “affiliate” means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(13) The term “establishment subject to a registration fee” means an establishment that is required to register with the Secretary under section 360 of this title and is one of the following types of establishments:

(A) Manufacturer

An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

(B) Single-use device reprocessor

An establishment that, within the meaning of section 321(l)(2)(A) of this title, performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

(C) Specification developer

An establishment that develops specifications for a device that is distributed under the establishment’s name but which performs no manufacturing, including an estab-
lishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment’s name by a contract manufacturer.


AMENDMENT OF SECTION

For termination of amendment by section 217 of Pub. L. 110–85, see Effective and Termination Dates of 2007 Amendment note below.

TERMINATION OF SECTION

For termination of section by section 107 of Pub. L. 107–250, see Effective and Termination Dates note set out below.

AMENDMENTS


 Pars. (5) to (9). Pub. L. 110–85, §§211(2), (3), 217, temporarily added pars. (5) to (7) and redesignated former pars. (5) and (6) as (8) and (9), respectively. Former pars. (7) and (8) redesignated (10) and (12), respectively. See Effective and Termination Dates of 2007 Amendment note below.

 Par. (10). Pub. L. 110–85, §§211(2), (4), 217, temporarily redesignated par. (7) as (10) and substituted “October of the preceding fiscal year” for “April of the preceding fiscal year” and “October 2001” for “April 2002.” See Effective and Termination Dates of 2007 Amendment note below.


 Par. (4)(B). Pub. L. 108–214, §2(a)(1)(A), substituted “and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness” for “for which substantial clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness”.


 Par. (5)(J). Pub. L. 108–214, §2(a)(1)(C), substituted “a premarket application or premarket report under section 360e of this title or a premarket application under section 262 of title 42” for “a premarket application under section 360e of this title or section 262 of title 42”.

 Par. (8). Pub. L. 108–214, §2(a)(1)(D), substituted “The term ‘affiliate’ means a business entity that has a relationship with a second business entity (whether domestic or international)” for “The term ‘affiliated business entity’ means a business entity that has a relationship with a second business entity”.

 EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

Pub. L. 110–85, title II, §216, Sept. 27, 2007, 121 Stat. 852, provided that: “The amendments made by this subtitle (subtitle A (§§211–217) of title II of Pub. L. 110–85, enacting section 379–1 of this title and amending this section and section 379) of this title shall take effect on October 1, 2007, or the date of the enactment of this Act (Sept. 27, 2007), whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1, 2007, regardless of the date of the enactment of this Act.”


EFFECTIVE AND TERMINATION DATES

Pub. L. 110–250, title I, §106, Oct. 26, 2002, 116 Stat. 1602, provided that: “The amendments made by this title [enacting section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) [set out as an Effective and Termination Dates note above], and notwithstanding the amendments made by this subtitle [subtitle A (§§211–217) of title II of Pub. L. 110–85, enacting section 379–1 of this title and amending this section and section 379) of this title], part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379 et seq.), as in effect on the day before the date of the enactment of this subtitle [Sept. 27, 2007], shall continue to be in effect with respect to all applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.”

FINDINGS

Pub. L. 110–85, title II, §201(c), Sept. 27, 2007, 121 Stat. 842, provided that: “The Congress finds that the fees authorized under the amendments made by this title [enacting section 379–1 of this title and amending this section and sections 333, 360, 360i, 360m, 374, and 379] of this title] will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.”


(1) prompt approval and clearance of safe and effective devices is critical to the improvement of the...
§ 379j. Authority to assess and use device fees

(a) Types of fees

(1) In general

Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section.

(2) Premarket application, premarket report, supplement, and submission fee, and annual fee for periodic reporting concerning a class III device

(A) In general

Except as provided in subparagraph (B) and subsections (d) and (e) of this section, each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(1) of this section for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel track supplement, a fee equal to 75 percent of the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 15 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7 percent of the fee that applies under clause (i).

(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).

(vii) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(viii) For a premarket notification submission, a fee equal to 1.64 percent of the fee that applies under clause (i).

(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).

(B) Exceptions

(i) Humanitarian device exemption

An application under section 360(m) of this title is not subject to any fee under subparagraph (A).

(ii) Further manufacturing use

No fee shall be required under subparagraph (A) for the submission of a premarket application under section 362 of title 21 for a product licensed for further manufacturing use only.

(iii) State or Federal Government sponsors

No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, or premarket notification submission submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

(iv) Premarket notifications by third parties

No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 360m of this title.

(v) Pediatric conditions of use

(I) In general

No fee shall be required under subparagraph (A) for a premarket application,
premarket report, or premarket notification submission if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

(II) Subsequent proposal of adult conditions of use

In the case of a person who submits a premarket application or premarket report for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

(C) Payment

The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 360e(c)(4) of this title shall pay such fees upon submission of the first portion of such applications.

(D) Refunds

(i) Application refused for filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

(ii) Application withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

(iii) Application withdrawn before first action

After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement.

(iv) Modular applications withdrawn before first action

The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 360e(c)(4) of this title that is withdrawn before a second portion is submitted and before a first action on the first portion.

(v) Later withdrawn modular applications

If an application submitted under section 360e(c)(4) of this title is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

(vi) Sole discretion to refund

The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.

(3) Annual establishment registration fee

(A) In general

Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 360 of this title beginning with its registration for fiscal year 2008.

(B) Exception

No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act\(^1\) [25 U.S.C. 450 et seq.], unless a device manufactured by the establishment is to be distributed commercially.

(C) Payment

The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 360 of this title.

(b) Fee amounts

Except as provided in subsections (c), (d), (e), and (h) the fees under subsection (a) shall be based on the following fee amounts:

<table>
<thead>
<tr>
<th>Fee Type</th>
<th>Fiscal Year 2008</th>
<th>Fiscal Year 2009</th>
<th>Fiscal Year 2010</th>
<th>Fiscal Year 2011</th>
<th>Fiscal Year 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premarket Application</td>
<td>$185,000</td>
<td>$200,725</td>
<td>$217,787</td>
<td>$236,298</td>
<td>$256,384</td>
</tr>
<tr>
<td>Establishment Registration</td>
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<td>$1,851</td>
<td>$2,008</td>
<td>$2,179</td>
<td>$2,364</td>
</tr>
</tbody>
</table>

\(^1\) See References in Text note below.
(c) Annual fee setting

(1) In general

The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, publish in the Federal Register fees under subsection (a) of this section.

(2) Adjustment

(A) In general

When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,750. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

(B) Publication

For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary’s determination to make the adjustment and the rationale for the determination.

(3) Limit

The total amount of fees charged, as adjusted under this subsection, 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 device applications.

(4) Supplement

(A) In general

The Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of the next fiscal year.

(B) Notice to Congress

Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(d) Small businesses; fee waiver and fee reduction regarding premarket approval fees

(1) In general

The Secretary shall grant a waiver of the fee required under subsection (a) of this section for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. For the purposes of this paragraph, the term “small business” means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) Rules relating to premarket approval fees

(A) Definition

For purposes of this paragraph, the term “small business” means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) Evidence of qualification

(i) In general

An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate.

(ii) Firms submitting tax returns to the United States Internal Revenue Service

The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) Firms not submitting tax returns to the United States Internal Revenue Service

In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is
headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant’s or affiliate’s gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant’s firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) Reduced fees
Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or periodic reporting concerning a class III device; and

(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.

(D) Request for fee waiver or reduction
An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a) of this section. The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

(e) Small businesses; fee reduction regarding premarket notification submissions
(1) In general
For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(viii) of this section may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) Rules relating to premarket notification submissions
(A) Definition
For purposes of this subsection, the term “small business” means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) Evidence of qualification
(i) In general
An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

(ii) Firms submitting tax returns to the United States Internal Revenue Service
The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) Firms not submitting tax returns to the United States Internal Revenue Service
In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant’s or affiliate’s gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant’s firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) Reduced fees
For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).

(D) Request for reduction
An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a) of this section. The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

(f) Effect of failure to pay fees
(1) No acceptance of submissions
A premarket application, premarket report, supplement, premarket notification submis-
sion, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

(2) No registration

Registration information submitted under section 360 of this title by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 360 of this title.

(g) Conditions

(1) Performance goals; termination of program

With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $305,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

(B) fees were not assessed under subsection (a) for the previous fiscal year.

(2) Authority

If the Secretary does not assess fees under subsection (a) 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 premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(h) Crediting and availability of fees

(1) In general

Fees authorized under subsection (a) of this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

(2) Collections and appropriation acts

(A) In general

The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device 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, excluding costs paid from fees collected under this section, for fiscal year 2002 multiplied by the adjustment factor.

(B) Compliance

(i) In general

The Secretary shall be considered to have met the requirements of subparagraph (A)(i) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of device applications—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(bb) such costs are not more than 5 percent below the level specified in such subparagraph.

(ii) More than 5 percent

To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

(3) Authorization of appropriations

There are authorized to be appropriated for fees under this section—

(A) $48,431,000 for fiscal year 2008;

(B) $52,547,000 for fiscal year 2009;

(C) $57,014,000 for fiscal year 2010;

(D) $61,860,000 for fiscal year 2011; and

(E) $67,118,000 for fiscal year 2012.

(4) Offset

If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be sub-
tracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.

(i) 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.

(j) Written requests for refunds

To qualify for consideration for a refund under subsection (a)(2)(D) of this section, a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

(k) 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, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(AMENDMENT OF SECTION)

For termination of amendment by section 217 of Pub. L. 110–85, see Effective and Termination Dates of 2007 Amendment note below.

(TERMINATION OF SECTION)

For termination of section by section 107 of Pub. L. 110–85, see Effective and Termination Dates note set out under section 379j of this title.

(REFERENCES IN TEXT)


(AMENDMENTS)


Subsec. (a)(2)(A)(iii). Pub. L. 110–85, §§212(a)(2)(A), 217, temporarily substituted “a fee equal to 75 percent of the fee that applies for a fee equal to the fee that applies” for “a fee equal to the fee that applies”. See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (a)(2)(A)(vii). Pub. L. 110–85, §§212(a)(2)(D), (F), 217, temporarily redesignated cl. (vii) as (viii), and struck out “subject to any adjustment under subsection (e)(2)(C)(ii) of this section” before period at end. See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (b). Pub. L. 110–85, §§212(b), 217, temporarily amended subsec. (b) generally. Prior to amendment, text read as follows: “Except as provided in subsections (c), (d), (e), (g), and (h) of this section, the fees under subsection (a) of this section shall be established to generate the following revenue amounts: $25,125,000 in fiscal year 2003; $27,255,000 in fiscal year 2004; and $29,785,000 in fiscal year 2005. If legislation is enacted after October 26, 2002, requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.” See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (c)(1). Pub. L. 110–85, §§212(c)(1)(B), 217, temporarily struck out at end “The fees established for fiscal year 2006 shall be based on a premarket application fee of $259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of $281,600.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2). Subsec. (c), Pub. L. 110–85, §§212(c)(2)(A), (B), 217, temporarily added par. (2) and redesignated former
§ 379j
TITLED—FOOD AND DRUGS

par. (2) as (3). Former par. (3) redesignated (4). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(4). Pub. L. 110–85, §§ 212(c)(2)(A), (C), 217, temporarily redesignated par. (3) as (4) and substituted in subpar. (A) “The Secretary” for “For fiscal years 2006 and 2007, the Secretary” and for the first month of the current fiscal year” for “for the first month of the fiscal year 2008”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(1). Pub. L. 110–85, §§ 212(d)(1), 217, temporarily struck out “partners, and parent firms” after “affiliates” and substituted “clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)” for “clauses (i) through (vi) of subsection (a)(2)(A) of this section”. See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (d)(2)(B). Pub. L. 110–85, §§ 212(d)(2)(B)(i), (ii), 217, temporarily designated first sentence as cl. (i) and second to fourth sentences as cl. (ii) and inserted cl. headings. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(B)(i). Pub. L. 110–85, §§ 212(d)(2)(B)(i), (iv), 217, temporarily struck out “partners, and parent firms” after “its affiliates” and after “such affiliates” and substituted “If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates, partners, or parent firms” for “If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.” See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (d)(2)(C). Pub. L. 110–85, §§ 212(d)(3), 217, temporarily amended subpar. (C) generally. Prior to amendment, text read as follows: “Where the Secretary finds that the applicant involved meets the definition of a premarket application, a premarket report, or a supplement.” See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (e)(2)(B)(ii). Pub. L. 110–85, §§ 212(e)(2)(B)(ii), (iv), 217, temporarily struck out “partners, and parent firms” after “its affiliates” and after “such affiliates” and substituted “If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates, partners, or parent firms” for “If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.” See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (e)(2)(C). Pub. L. 110–85, §§ 212(e)(2)(C), 217, temporarily amended subpar. (C) generally. Prior to amendment, text read as follows: “If no tax forms are submitted for fiscal years 2006 and 2007, the Secretary” and “for the first month of fiscal year” for “for the first month of fiscal year 2008”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(D). Pub. L. 110–85, §§ 212(e)(2)(D), 217, temporarily amended par. (2) generally. Prior to amendment, text read as follows: “A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.” See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(1). Pub. L. 110–85, §§ 212(g)(1), 217, temporarily added par. (1) and struck out former par. (1). Prior to amendment, par. (1) related to performance goals for fiscal years 2003 through 2005, with respect to the amount appropriated under the salaries and expenses account of the Food and Drug Administration, for devices and radiological products, and termination of the program after fiscal year 2005. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(2). Pub. L. 110–85, §§ 212(g)(2), 217, temporarily amended par. (2) generally. Prior to amendment, text read as follows: “If the Secretary does not assess fees under subsection (a) of this section during a fiscal year because of subparagraph (C) or (D) 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 premarket applications, supplements, premarket reports, and premarket notification submissions, and 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.” See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (h)(4). Pub. L. 110–85, §§ 212(h)(2), 217, temporarily amended par. (4) generally. Prior to amendment, text read as follows: “Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.” See Effective and Termination Dates of 2007 Amendment note below.


Subsec. (c)(1). Pub. L. 109–43, § 2(a)(2)(B)–(D), redesignated par. (5) as (1), substituted “In general” for “Annual fee setting” in heading, “publish in the Federal Register fees under subsection (a) of this section. The fees” for “establish, for the next fiscal year, and publish in the Federal Register fees under subsection (a) of this section. The fees” for “Annual fee setting”, “publish in the Federal Register fees under subsection (a) of this section. The fees” for “establish, for the next fiscal year, and publish in the Federal Register fees under subsection (a) of this section. The fees” for “Annual fee setting”, “publish in the Federal Register fees under subsection (a) of this section. The fees” for “establish, for the next fiscal year, and publish in the Federal Register fees under subsection (a) of this section. The fees” for “Annual fee setting”, “publish in the Federal Register fees under subsection (a) of this section. The fees” for “establish, for the next fiscal year, and publish in the Federal Register fees under subsection (a) of this section. The fees” for “Annual fee setting”, “publish in the Federal Register fees under subsection (a) of this section. The fees” for “establish, for the next fiscal year, and publish in the Federal Register fees under subsection (a) of this section. The fees”. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2). Pub. L. 109–43, § 2(a)(2)(B), (C), temporarily amended par. (6) as (2) and struck out former par. (2) which required an annual adjustment of the fees revenues ce-
established in subsec. (b) to reflect changes in the workload of the Secretary for the process for the review of device applications.

Subsec. (c)(3). Pub. L. 109–43, §2(a)(2)(B), added par. (3) and struck out former par. (3) which required an annual compensating adjustment of the fee revenues established in subsec. (b).

Subsec. (c)(4). Pub. L. 109–43, §2(a)(2)(B), struck out par. (4) which provided for a fiscal year 2007 adjustment of the fee revenues established in subsec. (b) to provide for operating reserves of carryover user fees and to decrease fees appropriated for such fiscal years, is equal to or less than the sum that applies under clause (i) for fiscal year 2005, the following applies: ''For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year, including such returns of all of its affiliates, parents, and parent firms.''

Subsec. (d)(2)(A). Pub. L. 109–43, §2(a)(2)(A)(ii), struck out clause (i) designation and heading before “For purposes”, substituted “paragraph” for “subsection,” and “$100,000,000” for “$30,000,000”, and struck out heading and text of clause (ii). Text read as follows: “The Secretary may adjust the $30,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 16 percent or more than would occur without small business exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.”


Subsec. (g)(1). Pub. L. 109–43, §2(a)(5)(A)(i), added cl. (i) and struck out former cl. (i) which read as follows: “For fiscal year 2006, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

‘‘(I) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

‘‘(II) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

‘‘(III) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.’’

Subsec. (g)(1)(B)(ii). Pub. L. 109–43, §2(a)(5)(A)(ii), added introductory provisions and struck out former introductory provisions which read as follows: “For fiscal year 2008, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:”.

Subsec. (g)(1)(C). Pub. L. 109–43, §2(a)(5)(B)(i), substituted “2005” and “2007” and inserted “more than 1 percent” after “years, is”. Subsec. (g)(1)(C)(i). Pub. L. 109–43, §2(a)(5)(B)(ii), substituted “amount that applies” for “sum that applies”. Subsec. (g)(1)(D)(i). Pub. L. 109–43, §2(a)(5)(C), inserted “more than 1 percent” after “years, is”. Sub. L. 109–43, §2(a)(6), added subpar. (D) and struck out former subpars. (D) and (E) which read as follows: “(D) $32,615,000 for fiscal year 2006; and

(E) $35,000,000 for fiscal year 2007.’’


Subsec. (a). Pub. L. 108–214, §2(d)(2)(A), designated introductory provisions of subsec. (a) as par. (1), inserted heading, substituted “this section,” for “this section as follows:”, and redesignated former par. (1) as (2). Subsec. (a)(1)(A). Pub. L. 108–214, §2(a)(2)(A)(ii), substituted, in introductory provisions, “subsections (d) and (e)” for “subsection (d)”, in cl. (iv), “clause (i)” for “clause (i), subject to any adjustment under subsection (c)(3) of this section”, and, in cl. (vii), “clause (i), subject to any adjustment under subsection (c)(3) of this section and any adjustment under subsection (e)(2)(C)(ii).”


Subsec. (h)(2)(B). Pub. L. 108–214, §2(a)(2)(E), designated existing provisions as cl. (i), inserted heading, redesignated former cl. (i) and (ii) as subscls. (I) and (II), respectively, of cl. (i), redesignated former subscls. (I) and (II) of cl. (i) as items (aa) and (bb), respectively, of cl. (I)(i), and added cl. (ii).


EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT


EFFECTIVE AND TERMINATION DATES


FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS


‘‘(1) the premarket report is the first such report submitted to the Secretary by the person; and

‘‘(2) before October 1, 2002, the person submitted a premarket application to the Secretary for the same device as the device for which the person is submitting the premarket report.”
during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) Fiscal report
For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(3) Public availability
The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

(b) Reauthorization

(1) Consultation
In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—
(A) the Committee on Energy and Commerce of the House of Representatives;
(B) the Committee on Health, Education, Labor, and Pensions of the Senate;
(C) scientific and academic experts;
(D) health care professionals;
(E) representatives of patient and consumer advocacy groups; and
(F) the regulated industry.

(2) Prior public input
Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—
(A) publish a notice in the Federal Register requesting public input on the reauthorization;
(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);
(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and
(D) publish the comments on the Food and Drug Administration’s Internet Web site.

(3) Periodic consultation
Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

(4) Public review of recommendations
After negotiations with the regulated industry, the Secretary shall—
(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;
(B) publish such recommendations in the Federal Register;
(C) provide for a period of 30 days for the public to provide written comments on such recommendations;
(D) hold a meeting at which the public may present its views on such recommendations; and
(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) Transmittal of recommendations
Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) Minutes of negotiation meetings
(A) Public availability
Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) Content
The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.


TERMINATION OF SECTION
For termination of section by section 217 of Pub. L. 110–85, see Effective and Termination Dates note below.

REFERENCES IN TEXT
Section 201(c) of the Food and Drug Administration Amendments Act of 2007, referred to in subsec. (a)(1), is...
section 201(c) of Pub. L. 110–85, which is set out as a note under section 379i of this title.

**Effective and Termination Dates**

Section effective Oct. 1, 2007, except for certain pre-market fees under this subpart, and ceases to be effective Jan. 31, 2013, see sections 216 and 217 of Pub. L. 110–85, set out as Effective and Termination Dates of 2007 Amendment notes under section 379i of this title.

**SUBPART 4—FEES RELATING TO ANIMAL DRUGS**

**Termination of Subpart**

For termination of subpart by section 5 of Pub. L. 108–130, see Termination Date note set out under section 379j–11 of this title.

For savings provisions, see section 106 of Pub. L. 110–316, set out as a note under section 379j–11 of this title.

**§ 379j–11. Definitions**

For purposes of this subpart:

(1) The term “animal drug application” means an application for approval of any new animal drug submitted under section 360b(b)(1) of this title. Such term does not include either a new animal drug application submitted under section 360b(b)(2) of this title or a supplemental animal drug application.

(2) The term “supplemental animal drug application” means:

(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 360b(c)(2) of this title for which data with respect to safety or effectiveness are required.

(3) The term “animal drug product” means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

(4) The term “animal drug establishment” means a foreign or domestic place of business which is 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 animal drug products are manufactured in final dosage form.

(5) The term “investigational animal drug submission” means—

(A) the filing of a claim for an investigational exemption under section 360b(j) of this title for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

(6) The term “animal drug sponsor” means either an applicant named in an animal drug application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

(7) The term “final dosage form” means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

(8) The term “process for the review of animal drug applications” means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary’s review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.

(9) The term “costs of resources allocated for the process for the review of animal drug applications” means the expenses incurred in connection with the process for the review of animal drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions,
and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,

(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 379j–12 of this title and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(10) The term “adjustment factor” applicable to a fiscal year refers to the formula set forth in section 379g(11) of this title.

(11) The term “person” includes an affiliate thereof.

(12) The term “affiliate” refers to the definition set forth in section 379g(11) of this title.


(b) Reporting Requirements.—The provisions made by section 104 [enacting section 379j–13 of this title] cease to be effective January 31, 2014.”

EFFECTIVE DATE OF 2007 AMENDMENT


TERMINATION DATE

Pub. L. 108–130, § 5, Nov. 18, 2003, 117 Stat. 1371, provided that: “The amendments made by section 3 [enacting this subpart] shall not be in effect after October 1, 2008, and section 4 [enacting provisions set out as a note below] shall not be in effect after 120 days after such date.”

SAVINGS PROVISIONS

Pub. L. 110–316, title I, § 106, Aug. 14, 2008, 122 Stat. 3514, provided that: “Notwithstanding section 3 of the Animal Drug User Fee Act of 2003 [Pub. L. 108–130] [21 U.S.C. 379j–11 note], and notwithstanding the amendments made by this title [enacting section 379j–13 of this title and amending this section and sections 360b and 379j–12 of this title], part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–11 et seq.], as in effect on the day before the date of the enactment of this title [Aug. 14, 2008], shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such date) that on or after September 1, 2003, but before October 1, 2008, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2009.”

FINDINGS


Pub. L. 108–130, § 2, Nov. 18, 2003, 117 Stat. 1361, provided that: “Congress finds as follows:

“(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

“(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and

AMENDMENT


(b) Reporting Requirements.—The provisions made by section 104 [enacting section 379j–13 of this title] cease to be effective January 31, 2014.”

EFFECTIVE AND TERMINATION DATES OF 2007 AMENDMENT

AMENDMENT


TERMINATION DATE

Pub. L. 108–130, § 5, Nov. 18, 2003, 117 Stat. 1371, provided that: “The amendments made by section 3 [enacting this subpart] shall not be in effect after October 1, 2008, and section 4 [enacting provisions set out as a note below] shall not be in effect after 120 days after such date.”

SAVINGS PROVISIONS

Pub. L. 110–316, title I, § 106, Aug. 14, 2008, 122 Stat. 3514, provided that: “Notwithstanding section 3 of the Animal Drug User Fee Act of 2003 [Pub. L. 108–130] [21 U.S.C. 379j–11 note], and notwithstanding the amendments made by this title [enacting section 379j–13 of this title and amending this section and sections 360b and 379j–12 of this title], part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–11 et seq.], as in effect on the day before the date of the enactment of this title [Aug. 14, 2008], shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such date) that on or after September 1, 2003, but before October 1, 2008, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2009.”

FINDINGS


Pub. L. 108–130, § 2, Nov. 18, 2003, 117 Stat. 1361, provided that: “Congress finds as follows:

“(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

“(2) Animal health and 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 new animal drug applications.

"(3) The fees authorized by this Act [enacting this subpart and provisions set out as notes under this section and section 301 of this title] will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.''

ACCOUNTABILITY AND REPORTS

Pub. L. 108–130, § 4, Nov. 18, 2003, 117 Stat. 1370, which required the Secretary of Health and Human Services, after certain consultations, to develop recommendations relating to the review of animal drug applications after fiscal year 2008, to submit to congressional committees a report each fiscal year concerning the progress of the Food and Drug Administration in achieving certain goals toward expediting the animal drug development process and the review of the animal drug applications and investigational animal drug submissions, and to submit a report for each fiscal year to congressional committees on the implementation of the authority for the fees collected under this subpart during the fiscal year and the use, by the Food and Drug Administration, of the fees collected, ceased to be effective 120 days after Oct. 1, 2008. See Termination Date note above.

§ 379j–12. Authority to assess and use animal drug fees

(a) Types of fees

Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Animal drug application and supplement fee

(A) In general

Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (b) of this section for an animal drug application, except an animal drug application subject to the criteria set forth in section 360b(d)(4) of this title; and

(ii) A fee established in subsection (b), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

(I) a supplemental animal drug application for which safety or effectiveness data are required; and

(II) an animal drug application subject to the criteria set forth in section 360b(d)(4) of this title.

(B) Payment

The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

(C) Exception for previously filed application or supplement

If an animal drug application or a supplemental animal drug application 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 or refund), the submission of an animal drug application or a supplemental animal drug application 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 refused for filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

(E) Refund of fee if application withdrawn

If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under paragraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) Animal drug product fee

Each person—

(A) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 360 of this title, and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application;

shall pay for each such animal drug product the annual fee established in subsection (b) of this section. Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

(3) Animal drug establishment fee

Each person—

(A) who owns or operates, directly or through an affiliate, an animal drug establishment, and

(B) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 360 of this title, and

(C) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,
shall be assessed an annual fee established in subsection (b) of this section for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee shall be paid on or before January 31 of each year. The establishment shall be assessed only one fee per fiscal year under this section: Provided, however, that where a single establishment manufactures both animal drug products and prescription drug products, as defined in section 379g(3) of this title, such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 379h(a)(2) of this title, within a single fiscal year.

(4) Animal drug sponsor fee

Each person—

(A) who meets the definition of an animal drug sponsor within a fiscal year; and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual fee established under subsection (b) of this section. The fee shall be paid on or before January 31 of each year. Each animal drug sponsor shall pay only one such fee each fiscal year.

(b) Fee amounts

Except as provided in subsection (a)(1) of this section and subsections (c), (d), (f), and (g) of this section, the fees required under subsection (a) of this section shall be established to generate fee revenue amounts as follows:

(1) Total fee revenues for application and supplement fees

The total fee revenues to be collected in animal drug application fees under subsection (a)(1)(A)(i) of this section and supplemental and other animal drug application fees under subsection (a)(1)(A)(ii) of this section shall be $3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.

(2) Total fee revenues for product fees

The total fee revenues to be collected in product fees under subsection (a)(2) of this section shall be $3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.

(3) Total fee revenues for establishment fees

The total fee revenues to be collected in establishment fees under subsection (a)(3) of this section shall be $3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.

(4) Total fee revenues for sponsor fees

The total fee revenues to be collected in sponsor fees under subsection (a)(4) of this section shall be $3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013.

(e) Adjustments

(1) Workload adjustment

The fee revenues shall be adjusted each fiscal year after fiscal year 2009 to reflect changes in review workload. With respect to such adjustment:

(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b) of this section.

(2) Final year adjustment

For fiscal year 2013, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2014. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2013.

(3) Annual fee setting

The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) of this section and the adjustments provided under this subsection.

(4) Limit

The total amount of fees charged, as adjusted under this subsection, 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 animal drug applications.
(d) Fee waiver or reduction

(1) In general

The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) of this section where the Secretary finds that—

(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances.

(B) 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 animal drug applications for such person.

(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds, or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation));

(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication, or

(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

(2) Use of standard costs

In making the finding in paragraph (1)(B), the Secretary may use standard costs.

(3) Rules for small businesses

(A) Definition

In paragraph (1)(E), the term “small business” means an entity that has fewer than 500 employees, including employees of affiliates.

(B) Waiver of application fee

The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

(C) Certification

The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

(e) Effect of failure to pay fees

An animal drug application or supplemental animal drug application 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. An investigational animal drug submission under section 379j–11(5)(B) of this title that is submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(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 2003 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 2003 (excluding the amount of fees appropriated for such fiscal year) 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 animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal 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 authorized under subsection (a) of this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

(2) Collections and appropriation acts

(A) In general

The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount speci-
§ 379j–12

(a) of this section within 30 days after it is due, and

(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal 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, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

(B) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(3) Authorization of appropriations

There are authorized to be appropriated for fees under this section

(A) $13,200,000 for fiscal year 2009;

(B) $17,280,000 for fiscal year 2010;

(C) $19,448,000 for fiscal year 2011;

(D) $21,768,000 for fiscal year 2012; and

(E) $24,244,000 for fiscal year 2013;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees.

(4) Offset

If the sum of the cumulative amount of fees collected under this section for fiscal years 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2013.

(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) Written requests for waivers, reductions, and refunds

To qualify for consideration for a waiver or reduction under subsection (d) of this section, or for a refund of any fee collected in accordance with subsection (a) of this section, a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) 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, employees, and advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) Abbreviated new animal drug applications

The Secretary shall—

(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications, and

(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.

(6) Fees

For savings provisions, see section 106 of Pub. L. 108–130, set out as a note under section 379j–11 of this title.

AMENDMENT OF SECTION

For termination of amendment by section 108(a) of Pub. L. 110–316, see Effective and Termination Dates of 2008 Amendment note below.

TERMINATION OF SECTION

For termination of section by section 5 of Pub. L. 110–316, see Termination Date note below.

For savings provisions, see section 106 of Pub. L. 110–316, set out as a note under section 379j–11 of this title.

AMENDMENTS


Subsec. (a)(1)(A)(ii). Pub. L. 110–316, §§103(a)(2), 108(a), temporarily amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: ‘‘A fee established in subsection (b) of this section for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i).’’ See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (b)(1). Pub. L. 110–316, §§103(b)(1), 108(a), temporarily substituted ‘‘and supplemental and other animal drug application fees’’ for ‘‘and supplemental animal drug application fees’’ and ‘‘$3,815,000 for fiscal year 2009, $4,320,000 for fiscal year 2010, $4,862,000 for fiscal year 2011, $5,442,000 for fiscal year 2012, and $6,061,000 for fiscal year 2013’’ for ‘‘$1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years


Subsec. (c)(1). Pub. L. 110–316, §§103(c)(1)–(3), 108(a), temporarily redesignated par. (2) as (1), substituted “‘The fee revenues shall be adjusted each fiscal year after fiscal year 2004’” for “‘After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004’” in introductory provisions, struck out “‘, as adjusted for inflation under paragraph (1) before period in subpar. (B), and struck out former par. (1) relating to inflation adjustment. See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(2). Pub. L. 110–316, §§103(c)(2), (4), 108(a), temporarily redesignated par. (3) as (2) and substituted “‘2013’ for ‘2008’ in two places and ‘2014’ for ‘2009’.” Former par. (2) redesignated (1). See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (c)(3). Pub. L. 110–316, §§103(c)(3), 108(a), temporarily redesignated par. (4) as (3) and (4), respectively. Former par. (3) redesignated (2). See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (g)(3)(A) to (E). Pub. L. 110–316, §§103(d), 108(a), temporarily amended subpars. (A) to (E) generally. Prior to amendment, subpars. (A) to (E) read as follows:

“(A) $5,000,000 for fiscal year 2004;
“(B) $8,000,000 for fiscal year 2005;
“(C) $10,000,000 for fiscal year 2006;
“(D) $10,000,000 for fiscal year 2007; and
“(E) $10,000,000 for fiscal year 2008.”.

See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (g)(4). Pub. L. 110–316, §§103(e), 108(a), temporarily amended par. (4) generally. Prior to amendment, par. (4) read as follows: “Any amount of fees specified in appropriations Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.” See Effective and Termination Dates of 2008 Amendment note below.

Subsec. (g)(5). Pub. L. 110–316, §§103(e)(2), 108(a), temporarily redesignated pars. (4) and (5) as (3) and (4), respectively. Former par. (3) redesignated (2). See Effective and Termination Dates of 2008 Amendment note below.

Effective and Termination Dates of 2008 Amendment

Amendment by Pub. L. 110–316 effective Oct. 1, 2008, with fees under this subpart to be assessed for all animal drug applications and supplemental animal drug applications received on or after Oct. 1, 2008, and ceases to be effective Oct. 1, 2013, as to fees under this subpart for fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

$379j–13. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Animal Drug User Fee Amendments of 2008 toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

(b) Fiscal report

Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications for the first 5 fiscal years after fiscal year 2013, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.
§ 379j–21 Prior public input

Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and

(D) publish the comments on the Food and Drug Administration’s Internet Web site.

(3) Periodic consultation

Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

(4) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) Transmittal of recommendations

Not later than January 15, 2013, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) Minutes of negotiation meetings

(A) Public availability

Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) Content

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.


TERMINATION OF SECTION

For termination of section by section 108(b) of Pub. L. 110–316, see Effective and Termination Dates note below.

REFERENCES IN TEXT

Section 101(b) of the Animal Drug User Fee Amendments of 2008, referred to in subsec. (a), is section 101(b) of Pub. L. 110–316, which is set out as a note under section 379j–11 of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 1, 2008, with fees under this subpart to be assessed for all animal drug applications and supplemental animal drug applications received on or after Oct. 1, 2008, and ceases to be effective Jan. 31, 2014, see sections 107 and 108(b) of Pub. L. 110–316, set out as Effective and Termination Dates of 2008 Amendment notes under section 379j–11 of this title.

SUBPART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

TERMINATION OF SUBPART

For termination of subpart by section 204 of Pub. L. 110–316, see Termination Date notes set out under sections 379j–21 and 379j–22 of this title.

§ 379j–21. Authority to assess and use generic new animal drug fees

(a) Types of fees

Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Abbreviated application fee

(A) In general

Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (b) for such an application.

(B) Payment

The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

(C) Exception for previously filed application

If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person’s assignee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) Refund of fee if application refused for filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.
(E) Refund of fee if application withdrawn

If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the withdrawal was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

(2) Generic new animal drug product fee

Each person—

(A) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 360 of this title, and

(B) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (b). Such fee shall be payable for the fiscal year in which the generic new animal drug product has been submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

(3) Generic new animal drug sponsor fee

(A) In general—

Each person—

(i) who meets the definition of a generic new animal drug sponsor within a fiscal year, and

(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual fee established under subsection (b). The fee shall be paid on or before January 31 of each year.

(B) Amount of fee

Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with more than 6 approved abbreviated applications.

(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with 1 or fewer approved abbreviated applications.

(b) Fee amounts

Except as provided in subsection (a)(1) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

(1) Total fee revenues for application fees

The total fee revenues to be collected in abbreviated application fees under subsection (a)(1) shall be $1,449,000 for fiscal year 2009, $1,532,000 for fiscal year 2010, $1,619,000 for fiscal year 2011, $1,712,000 for fiscal year 2012, and $1,809,000 for fiscal year 2013.

(2) Total fee revenues for product fees

The total fee revenues to be collected in generic new animal drug product fees under subsection (a)(2) shall be $1,691,000 for fiscal year 2009, $1,787,000 for fiscal year 2010, $1,889,000 for fiscal year 2011, $1,977,000 for fiscal year 2012, and $2,111,000 for fiscal year 2013.

(3) Total fee revenues for sponsor fees

The total fee revenues to be collected in generic new animal drug sponsor fees under subsection (a)(3) shall be $1,691,000 for fiscal year 2009, $1,787,000 for fiscal year 2010, $1,889,000 for fiscal year 2011, $1,997,000 for fiscal year 2012, and $2,111,000 for fiscal year 2013.

(c) Adjustments

(1) Workload adjustment

The fee revenues shall be adjusted each fiscal year after fiscal year 2009 to reflect changes in review workload. With respect to such adjustment:

(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b).

(2) Final year adjustment

For fiscal year 2013, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year 2014. If the Food and Drug Administration has carryover balances for the process for the review of abbreviated applications for generic new animal drugs in excess of 3 months of such operating reserves, then this adjustment shall not be made. If this adjustment is necessary, then the rationale for the amount of the in-
creased shall be contained in the annual notice setting fees for fiscal year 2013.

(3) Annual fee setting

The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2008, for that fiscal year, abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

(d) Fee waiver or reduction

The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

(e) Effect of failure to pay fees

An abbreviated application for a generic new animal drug submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational submission for a generic new animal drug that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(f) Assessment of fees

(1) Limitation

Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 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 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) Authority

If the Secretary does not assess fees under subsection (a) 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 abbreviated applications, generic new animal drug sponsors, and generic new animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) Crediting and availability of fees

(1) In general

Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

(2) Collections and appropriation acts

(A) In general

The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (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, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

(B) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of abbreviated applications for generic new animal drugs—

(1) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(2) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(3) Authorization of appropriations

There are authorized to be appropriated for fees under this section—

(A) $4,831,000 for fiscal year 2009.
(B) \$5,106,000 for fiscal year 2010;  
(C) \$5,397,000 for fiscal year 2011;  
(D) \$5,706,000 for fiscal year 2012; and  
(E) \$6,031,000 for fiscal year 2013;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees.

(4) Offset

If the sum of the cumulative amount of fees collected under this section for the fiscal years 2009 through 2011 and the amount of fees estimated to be collected under this section for fiscal year 2012 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2009 through 2012, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2013.

(h) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) 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) Written requests for waivers, reductions, and refunds

To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) 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, employees, and advisory committees not engaged in the process of the review of abbreviated applications for generic new animal drugs, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) Definitions

In this section and section 379j–22 of this title:

(1) Abbreviated application for a generic new animal drug

The terms “abbreviated application for a generic new animal drug” and “abbreviated application” mean an abbreviated application for the approval of any generic new animal drug submitted under section 360b(b)(2) of this title. Such term does not include a supplemental abbreviated application for a generic new animal drug.

(2) Adjustment factor

The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—  
(A) for purposes of subsection (f)(1), such Index for October 2002; and  
(B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

(3) Costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs

The term “costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs” means the expenses incurred in connection with the process for the review of abbreviated applications for generic new animal drugs for—  
(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;  
(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 this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(4) Final dosage form

The term “final dosage form” means, with respect to a generic new animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes generic new animal drug products intended for mixing in animal feeds.

(5) Generic new animal drug

The term “generic new animal drug” means a new animal drug that is the subject of an abbreviated application.

(6) Generic new animal drug product

The term “generic new animal drug product” means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved.

(7) Generic new animal drug sponsor

The term “generic new animal drug sponsor” means either an applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the
applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by the Secretary.

(8) Investigational submission for a generic new animal drug
The terms “investigational submission for a generic new animal drug” and “investigational submission” mean—
(A) the filing of a claim for an investigational exemption under section 360b(j) of this title for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or
(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

(9) Person
The term “person” includes an affiliate thereof (as such term is defined in section 379g(11) of this title).

(10) Process for the review of abbreviated applications for generic new animal drugs
The term “process for the review of abbreviated applications for generic new animal drugs” means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:
(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:
(B) The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.
(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary’s review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.
(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.
(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.
(F) Development of standards for products subject to review.
(G) Meetings between the agency and the generic new animal drug sponsor.
(H) Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

(11) Supplemental abbreviated application for generic new animal drug
The terms “supplemental abbreviated application for a generic new animal drug” and “supplemental abbreviated application” mean a request to the Secretary to approve a change in an approved abbreviated application.

Federal Register
For termination of section by section 204(a) of Pub. L. 110–316, see Termination Date note below.

Prior Provisions
A prior section 741 of act June 25, 1938, was renumbered section 745 and is classified to section 379k of this title.

Termination Date

Findings
(1) Prompt approval of abbreviated applications for safe and effective generic new animal drugs will reduce animal healthcare costs and promote the well-being of animal health and the public health.
(2) Animal health and 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 the review of abbreviated applications for the approval of generic new animal drugs.
(3) The fees authorized by this title [see Short Title of 2008 Amendment note set out under section 301 of this title] will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.”

§ 379j–22. Reauthorization; reporting requirements
(a) Performance reports
Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in sec-
tion 201(3) of the Animal Generic Drug User Fee Act of 2008 toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs during such fiscal year.

(b) Fiscal report

Beginning with fiscal year 2009, not later than 120 days after the end of each fiscal year during which fees are collected under this subpart, the Secretary shall prepare and submit to Congress a report on the implementation of the authority for fees collected during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs for the first 5 fiscal years after fiscal year 2013, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;
(B) the Committee on Health, Education, Labor, and Pensions of the Senate;
(C) scientific and academic experts;
(D) veterinary professionals;
(E) representatives of patient and consumer advocacy groups; and
(F) the regulated industry.

(2) Prior public input

Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;
(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);
(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and
(D) publish the comments on the Food and Drug Administration’s Internet Web site.

(3) Periodic consultation

Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

(4) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;
(B) publish such recommendations in the Federal Register;
(C) provide for a period of 30 days for the public to provide written comments on such recommendations;
(D) hold a meeting at which the public may present its views on such recommendations; and
(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) Transmittal of recommendations

Not later than January 15, 2013, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) Minutes of negotiation meetings

(A) Public availability

Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) Content

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

References in Text

Section 201(3) of the Animal Generic Drug User Fee Act of 2008, referred to in subsec. (a), probably means section 201(b)(3) of Pub. L. 110–316, which is set out as a note under section 379j–21 of this title.

Prior Provisions

A prior section 742 of act June 25, 1938, was renumbered section 746 and is classified to section 379j of this title.

Termination Date

SUBPART 6—FEES RELATED TO FOOD

§ 379j–31. Authority to collect and use fees

(a) In general

(1) Purpose and authority

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

(A) the responsible party for each domestic facility (as defined in section 350d(b) of this title) and the United States agent for each foreign facility subject to a reinspections in such fiscal year, to cover reinspections-related costs for such year;

(B) the responsible party for a domestic facility (as defined in section 350d(b) of this title) and an importer who does not comply with a recall order under section 350l of this title or under section 350a(f) of this title in such fiscal year, to cover food recall activities associated with such order performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for such year;

(C) each importer participating in the voluntary qualified importer program under section 384b of this title in such year, to cover the administrative costs of such program for such year; and

(D) each importer subject to a reinspections in such fiscal year, to cover reinspections-related costs for such year.

(2) Definitions

For purposes of this section—

(A) the term “reinspection” means—

(i) with respect to domestic facilities (as defined in section 350d(b) of this title), 1 or more inspections conducted under section 374 of this title subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction; and

(ii) with respect to importers, 1 or more examinations conducted under section 381 of this title subsequent to an examination conducted under such provision which identified noncompliance materially related to a food safety requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction;

(B) the term “reinspection-related costs” means all expenses, including administrative expenses, incurred in connection with—

(i) arranging, conducting, and evaluating the results of reinspections; and

(ii) assessing and collecting reinspections fees under this section; and

(C) the term “responsible party” has the meaning given such term in section 350f(a)(1) of this title.

(b) Establishment of fees

(1) In general

Subject to subsections (c) and (d), the Secretary shall establish the fees to be collected under this section for each fiscal year specified in subsection (a)(1), based on the methodology described under paragraph (2), and shall publish such fees in a Federal Register notice not later than 60 days before the start of each such year.

(2) Fee methodology

(A) Fees

Fees amounts established for collection—

(i) under subparagraph (A) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the reinspections-related activities (including by type or level of reinspections activity, as the Secretary determines applicable) described in such subparagraph (A) for such year;

(ii) under subparagraph (B) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the activities described in such subparagraph (B) for such year;

(iii) under subparagraph (C) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the activities described in such subparagraph (C) for such year; and

(iv) under subparagraph (D) of subsection (a)(1) for a fiscal year shall be based on the Secretary’s estimate of 100 percent of the costs of the activities described in such subparagraph (D) for such year.

(B) Other considerations

(i) Voluntary qualified importer program

In establishing the fee amounts under subparagraph (A)(iii) for a fiscal year, the Secretary shall provide for the number of importers who have submitted to the Secretary a notice under section 384b(c) of this title informing the Secretary of the intent of such importer to participate in the program under section 384b of this title in such fiscal year.

(II) Recoupment

In establishing the fee amounts under subparagraph (A)(iii) for the first 5 fiscal years after January 4, 2011, the Secretary shall provide for the recoupment of the costs expended by the Secretary to establish and implement the first year of the program under section 384b of this title.

(ii) Crediting of fees

In establishing the fee amounts under subparagraph (A) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of fees needed to carry out such

1 So in original. No subcl. (I) has been enacted.
activities, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

(ii) Published guidelines

Not later than 180 days after January 4, 2011, the Secretary shall publish in the Federal Register a proposed set of guidelines in consideration of the burden of fee amounts on small business. Such consideration may include reduced fee amounts for small businesses. The Secretary shall provide for a period of public comment on such guidelines. The Secretary shall adjust the fee schedule for small businesses subject to such fees only through notice and comment rulemaking.

(3) Use of fees

The Secretary shall make all of the fees collected pursuant to clause (i), (ii), (iii), and (iv) of paragraph (2)(A) available solely to pay for the costs referred to in such clause (i), (ii), (iii), and (iv) of paragraph (2)(A), respectively.

(e) Limitations

(1) In general

Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless the amount of the total appropriations for food safety activities at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) is equal to or greater than the amount of appropriations for food safety activities at the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year), multiplied by the adjustment factor under paragraph (3).

(2) Authority

If—

(A) the Secretary does not assess fees under subsection (a) for a portion of a fiscal year because paragraph (1) applies; and

(B) at a later date in such fiscal year, such paragraph (1) ceases to apply,

the Secretary may assess and collect such fees under subsection (a), without any modification to the rate of such fees, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(3) Adjustment factor

(A) In general

The adjustment factor described in paragraph (1) shall be the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year, but in no case shall such adjustment factor be negative.

(B) Compounded basis

The adjustment under subparagraph (A) made each fiscal year shall be added on a compounded basis to the sum of all adjust-

ements made each fiscal year after fiscal year 2009.

(4) Limitation on amount of certain fees

(A) In general

Notwithstanding any other provision of this section and subject to subparagraph (B), the Secretary may not collect fees in a fiscal year such that the amount collected—

(1) under subparagraph (B) of subsection (a)(1) exceeds $20,000,000; and

(ii) under subparagraphs (A) and (D) of subsection (a)(1) exceeds $25,000,000 combined.

(B) Exception

If a domestic facility (as defined in section 350d(b) of this title) or an importer becomes subject to a fee described in subparagraph (A), (B), or (D) of subsection (a)(1) after the maximum amount of fees has been collected by the Secretary under subparagraph (A), the Secretary may collect a fee from such facility or importer.

(d) Crediting and availability of fees

Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in appropriations Acts. Such fees are authorized to remain available until expended. Such sums transferred shall be available solely for the purpose of paying the operating expenses of the Food and Drug Administration employees and contractors performing activities associated with these food safety fees.

(e) Collection of fees

(1) In general

The Secretary shall specify in the Federal Register notice described in subsection (b)(1) the time and manner in which fees assessed under this section shall be collected.

(2) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under this section within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31.

(f) Annual report to Congress

Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for each such year and a summary description of the entities paying such fees and the types of business in which such entities engage.

(g) Authorization of appropriations

For fiscal year 2010 and each fiscal year thereafter, there is authorized to be appropriated for
fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under the other provisions of this section.


CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

PART D—INFORMATION AND EDUCATION

§ 379k. Information system

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.


AMENDMENT OF SECTION

For termination of amendment renumbering this section by section 204(a) of Pub. L. 110–316, see Termination Date of 2008 Amendment note below.

TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110–316, set out as a Termination Date note under section 379j–2 of this title.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT ON STATUS OF SYSTEM

Section 407(b) of Pub. L. 105–115 provided that not later than 1 year after Nov. 21, 1997, Secretary of Health and Human Services was to submit report to Congress on status of system to be established under this section, including projected costs of system and concerns about confidentiality.

§ 379l. Education

(a) In general

The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title;

(3) training to achieve product specialization in such inspections; and

(4) training in administrative process and procedure and integrity issues.

(b) Intramural fellowships and other training programs

The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians. Any such fellowships and training programs under this section or under section 379d(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.


AMENDMENT OF SECTION

For termination of amendment renumbering this section by section 204(a) of Pub. L. 110–316, see Termination Date of 2008 Amendment note below.

PRIOR PROVISIONS

A prior section 746 of act June 25, 1938, was renumbered section 749 and is classified to section 379o of this title.

AMENDMENTS

2007—Subsec. (b). Pub. L. 110–85 inserted at end “Any such fellowships and training programs under this section or under section 379d(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.”

TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110–316, set out as a Termination Date note under section 379j–2 of this title.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

PART E—ENVIRONMENTAL IMPACT REVIEW

§ 379b. Environmental impact

Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report related to) this chapter, shall be considered to meet the requirements for a detailed statement under section 4332(2)(C) of title 42.

(June 25, 1938, ch. 675, §749, formerly §746, as added Pub. L. 105–115, title IV, §411, Nov. 21, 1997,
(a) In general
Except as provided in subsection (b), (c), (d), (e), or (f) of this section, no State or political subdivision of a State may establish or continue in effect any requirement—
(1) that relates to the regulation of a drug that is not subject to the requirements of section 333(b)(1) or 333(f)(1)(A) of this title; and
(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) Exemption
(1) In general
Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—
(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;
(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and
(C) would not unduly burden interstate commerce.

(2) Timely action
The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

(e) Scope
(1) In general
This section shall not apply to—
(A) any State or political subdivision requirement that relates to the practice of pharmacy; or
(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

(2) Safety or effectiveness
For purposes of subsection (a) of this section, a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

(d) Exceptions
(1) In general
In the case of a drug described in subsection (a)(1) of this section that is not the subject of an application approved under section 355 of this title or section 357 of this title (as in effect on the day before November 21, 1997) or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) of this section shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—
(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2) of this section; or
(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after November 21, 1997.

(2) State initiatives
This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(e) No effect on product liability law
Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(f) State enforcement authority
Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this chapter.

(2) State initiatives
This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(e) No effect on product liability law
Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(f) State enforcement authority
Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this chapter.
§ 379s. Preemption for labeling or packaging of cosmetics

(a) In general

Except as provided in subsection (b), (d), or (e) of this section, no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) Exemption

Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or packaging that—

(1) protects an important public interest that would otherwise be unprotected;

(2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

(3) would not unduly burden interstate commerce.

(c) Scope

For purposes of subsection (a) of this section, a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this chapter for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

(d) No effect on product liability law

Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(e) State initiative

This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.


EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 379v. Safety report disclaimers

With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product that is a food, drug, device, dietary supplement, or cosmetic) under this chapter (and any release by the Secretary of that report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness.


EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

PART H—SERIOUS ADVERSE EVENT REPORTS

§ 379aa. Serious adverse event reporting for nonprescription drugs

(a) Definitions

In this section:

(1) Adverse event

The term “adverse event” means any health-related event associated with the use of a nonprescription drug that is adverse, including—

(A) an event occurring from an overdose of the drug, whether accidental or intentional;

(B) an event occurring from abuse of the drug;

(C) an event occurring from withdrawal from the drug; and

(D) any failure of expected pharmacological action of the drug.

(2) Nonprescription drug

The term “nonprescription drug” means a drug that is—
(A) not subject to section 353(b) of this title; and
(B) not subject to approval in an application submitted under section 355 of this title.

(3) Serious adverse event
The term “serious adverse event” is an adverse event that—
(A) results in—
(i) death;
(ii) a life-threatening experience;
(iii) inpatient hospitalization;
(iv) a persistent or significant disability or incapacity; or
(v) a congenital anomaly or birth defect; or
(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(4) Serious adverse event report
The term “serious adverse event report” means a report that is required to be submitted to the Secretary under subsection (b).

(b) Reporting requirement
(1) In general
The manufacturer, packer, or distributor whose name (pursuant to section 352(b)(1) of this title) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the “responsible person”) shall submit to the Secretary any report received of a serious adverse event associated with such drug.

(2) Retailer
A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the nonprescription drug to submit the required reports for such drugs to the Secretary so long as the retailer directs to submit the required reports for such drugs to the Secretary through the address or telephone number described in section 352(x) of this title.

(c) Submission of reports
(1) Timing of reports
The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 352(x) of this title.

(2) New medical information
The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

(3) Consolidation of reports
The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

(4) Exemption
The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

(d) Contents of reports
Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for nonprescription drugs, and may be accompanied by additional information.

(e) Maintenance and inspection of records
(1) Maintenance
The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

(2) Records inspection
(A) In general
The responsible person shall permit an authorized person to have access to records required to be maintained under this section, during an inspection pursuant to section 374 of this title.

(B) Authorized person
For purposes of this paragraph, the term “authorized person” means an officer or employee of the Department of Health and Human Services who has—
(i) appropriate credentials, as determined by the Secretary; and
(ii) been duly designated by the Secretary to have access to the records required under this section.

(f) Protected information
A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—
(1) a safety report under section 379v of this title and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and
(2) a record about an individual under section 552a of title 5 (commonly referred to as the “Privacy Act of 1974”) and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the “Freedom of Information Act”), and shall not be publicly disclosed unless all personally identifiable information is redacted.

(g) Rule of construction
The submission of any adverse event report in compliance with this section shall not be con-
§ 379aa–1  TITLE 21—FOOD AND DRUGS  Page 378

strued as an admission that the nonprescription drug involved caused or contributed to the adverse event.

(h) Preemption
(1) In general
No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for nonprescription drugs, that is different from, in addition to, or otherwise not identical to, this section.

(2) Effect of section
(A) In general
Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

(B) Personally-identifiable information
Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—
(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or
(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

(C) Use of safety reports
Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 379v of this title.

(i) Authorization of appropriations
There are authorized to be appropriated to carry out this section such sums as may be necessary.


EFFECTIVE DATE
Section effective 1 year after Dec. 22, 2006, see section 2(e)(1) of Pub. L. 109–462, set out as an Effective Date of 2006 Amendment note under section 322 of this title.

MODIFICATIONS
Pub. L. 109–462, §2(b), Dec. 22, 2006, 120 Stat. 3472, provided that: “The Secretary of Health and Human Services may modify requirements under the amendments made by this section [enacting this section and amending sections 322 and 323 of this title] in accordance with section 553 of title 5, United States Code, to maintain consistency with international harmonization efforts over time.”

GUIDANCE
Pub. L. 109–462, §2(e)(3), Dec. 22, 2006, 120 Stat. 3472, provided that: “Not later than 270 days after the date of enactment of this Act [Dec. 22, 2006], the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report described under the amendments made by this Act [see Short Title of 2006 Amendment note set out under section 301 of this title].”


§ 379aa–1. Serious adverse event reporting for dietary supplements

(a) Definitions
In this section:

(1) Adverse event
The term “adverse event” means any health-related event associated with the use of a dietary supplement that is adverse.

(2) Serious adverse event
The term “serious adverse event” is an adverse event that—
(A) results in—
(i) death;
(ii) a life-threatening experience;
(iii) inpatient hospitalization;
(iv) a persistent or significant disability or incapacity; or
(v) a congenital anomaly or birth defect; or
(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(3) Serious adverse event report
The term “serious adverse event report” means a report that is required to be submitted to the Secretary under subsection (b).

(b) Reporting requirement
(1) In general
A manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 343(e)(1) of this title) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the “responsible person”) shall submit to the Secretary any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement.

(2) Retailer
A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for such dietary supplements to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number described in section 343(y) of this title.

(c) Submission of reports
(1) Timing of reports
The responsible person shall submit to the Secretary a serious adverse event report no
later than 15 business days after the report is received through the address or phone number described in section 343(y) of this title.

(2) **New medical information**

The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

(3) **Consolidation of reports**

The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

(4) **Exemption**

The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

(d) **Contents of reports**

Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

(e) **Maintenance and inspection of records**

(1) **Maintenance**

The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

(2) **Records inspection**

(A) **In general**

The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 374 of this title.

(B) **Authorized person**

For purposes of this paragraph, the term “authorized person” means an officer or employee of the Department of Health and Human Services, who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been duly designated by the Secretary to have access to the records required under this section.

(f) **Protected information**

A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

(1) a safety report under section 379v of this title and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5 (commonly referred to as the “Privacy Act of 1974”) and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the “Freedom of Information Act”), and shall not be publicly disclosed unless all personally identifiable information is redacted.

(g) **Rule of construction**

The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.

(h) **Preemption**

(1) **In general**

No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is different from, in addition to, or otherwise not identical to, this section.

(2) **Effect of section**

(A) **In general**

Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

(B) **Personally-identifiable information**

Notwithstanding any other provision of law, personally-identifiable information in adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

(C) **Use of safety reports**

Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 379v of this title.

(i) **Authorization of appropriations**

There are authorized to be appropriated to carry out this section such sums as may be necessary.

§ 379dd  TITLE 21—FOOD AND DRUGS  Page 380

**Effective Date**
Section effective 1 year after Dec. 22, 2006, see section 3(d)(1) of Pub. L. 109–462, set out as an Effective Date of 2006 Amendment note under section 343 of this title.

**PART I—REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION**

§ 379dd. Establishment and functions of the Foundation

(a) In general
A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this part as the “Foundation”) shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) Purpose of Foundation
The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

(c) Duties of the Foundation
The Foundation shall—
(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and predictive tools and devices to measure safety;
(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);
(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;
(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of title 26 (and exempt from tax under section 501(a) of such title), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);
(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);
(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);
(7) ensure that—
(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;
(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation;
(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);
(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency’s public health mission;
(9) conduct annual assessments of the unmet needs identified in paragraph (1); and
(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

(d) Board of Directors
(1) Establishment

(A) In general
The Foundation shall have a Board of Directors (referred to in this part as the “Board”), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) Ex officio members
The ex officio members of the Board shall be the following individuals or their designees:
(i) The Commissioner.
(ii) The Director of the National Institutes of Health.
(iii) The Director of the Centers for Disease Control and Prevention.
(iv) The Director of the Agency for Healthcare Research and Quality.

(C) Appointed members
(i) In general
The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 14 individuals, of which 9 shall be from a list of candidates to be provided by the National Academy of Sciences and 5 shall be from
lists of candidates provided by patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations. Of such appointed members:

(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;
(II) 3 shall be representatives of academic research organizations;
(III) 2 shall be representatives of patient or consumer advocacy organizations;
(IV) 1 shall be a representative of health care providers; and
(V) 4 shall be at-large members with expertise or experience relevant to the purpose of the Foundation.

(ii) Requirements

(I) Expertise

The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

(II) Federal employees

No employee of the Federal Government shall be appointed as a member of the Board under this subparagraph or under paragraph (3)(B).

(D) Initial meeting

(i) In general

Not later than 30 days after September 27, 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation; and
(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) Service of ex officio members

Upon the appointment of the members of the Board under clause (i)(II)—

(I) the terms of service of the Director of the Centers for Disease Control and Prevention and of the Director of the Agency for Healthcare Research and Quality as ex officio members of the Board shall terminate; and
(II) the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board, but shall be nonvoting members.

(iii) Chair

The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

(2) Duties of Board

The Board shall—

(A) establish bylaws for the Foundation that—

(i) are published in the Federal Register and available for public comment;
(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;
(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;
(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18;
(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;
(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;
(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;
(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;
(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;
(x) specify a process for annual Board review of the operations of the Foundation; and
(xi) establish specific duties of the Executive Director;

(B) prioritize and provide overall direction to the activities of the Foundation;

(C) evaluate the performance of the Executive Director; and

(D) carry out any other necessary activities regarding the functioning of the Foundation.

(3) Terms and vacancies

(A) Term

The term of office of each member of the Board appointed under paragraph (1)(C) shall
be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

(B) Vacancy
Any vacancy in the membership of the Board—
(i) shall not affect the power of the remaining members to execute the duties of the Board; and
(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

(C) Partial term
If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) Serving past term
A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) Compensation
Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(e) Incorporation
The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(f) Nonprofit status
In carrying out subsection (b), the Board shall establish such policies and bylaws under subsection (d), and the Executive Director shall carry out such activities under subsection (g), as may be necessary to ensure that the Foundation maintains status as an organization that—
(1) is described in subsection (c)(3) of section 501 of title 26; and
(2) is, under subsection (a) of such section, exempt from taxation.

(g) Executive Director
(1) In general
The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) Compensation
The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

(h) Administrative powers
In carrying out this part, the Board, acting through the Executive Director, may—
(1) adopt, alter, and use a corporate seal, which shall be judicially noticed; (2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;
(3) prescribe the manner in which—
(A) real or personal property of the Foundation is acquired, held, and transferred;
(B) general operations of the Foundation are to be conducted; and
(C) the privileges granted to the Board by law are exercised and enjoyed;
(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;
(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;
(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);
(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;
(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;
(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;
(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;
(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and
(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(i) Acceptance of funds from other sources
The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

(j) Service of Federal employees
Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

(k) Detail of Government employees; fellowships
(1) Detail from Federal agencies
Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical,
and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

(2) Voluntary service; acceptance of Federal employees

(A) Foundation

The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

(B) Food and Drug Administration

The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 379 of this title.

(l) Annual reports

(1) Reports to Foundation

Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

(2) Report to Congress and the FDA

Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

(m) Separation of funds

The Executive Director shall ensure that the funds received from the Treasury are held in separate accounts from funds received from entities under subsection (l).

(n) Funding

From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than $500,000 and not more than $1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).

(6) \(500,000 \text{ and not more than } 1,250,000\), to the Commissioner shall transfer not less than Drug Administration for each fiscal year, the District of Columbia.

(June 25, 1938, ch. 675, § 771, as added Pub. L. 110–85, title VI, § 601(b), Sept. 27, 2007, 121 Stat. 897.)

§ 379dd-2. Activities of the Food and Drug Administration

(a) In general

The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 379dd(l)(2) of this title.

(b) Report to Congress

Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 379dd(l)(2) of this title and by other recipients of grants, contracts, memoranda of understanding, or cooperative agreements into regulatory and product review activities of the Food and Drug Administration.

(c) Extramural grants

The provisions of this part and section 360bbb–5 of this title shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the Food and Drug Administration and any other entity entered into before, on, or after September 27, 2007.

(June 25, 1938, ch. 675, § 772, as added Pub. L. 110–85, title VI, § 601(b), Sept. 27, 2007, 121 Stat. 897.)

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, tobacco products, 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 or section 387e(h) of this title and shall request that if any drugs, devices, or tobacco products 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, devices, or tobacco products 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 meth-