(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 methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title or the importer (as defined in section 384a of this title) is in violation of such section 384a of this title, or prohibited from introduction or delivery for introduction into interstate commerce under section 331(*ll*) of this title, or is a controlled substance subject to an order under section 360bbb–8d of this title, or (4) the recordkeeping requirements under section 2223 of this title (other than the requirements under subsection (f) of such section) have not been complied with regarding such article or[1] (5) such article is being imported or offered for import in violation of section 331(cc) of this title, then any such article described in any of clauses (1) through (5) shall be refused admission, except as provided in subsection (b) of this section. If it appears from the examination of such samples or otherwise that the article is a counterfeit drug or counterfeit device, such article shall be refused admission. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this chapter, then such article shall be refused admission. If such article is subject to a requirement under section 364a, 379aa, or 379aa–1 of this title and if the Secretary has credible evidence or information indicating that the responsible person (as defined in section 364, 379aa, or 379aa–1 of this title) has not complied with a requirement of such section 364a, 379aa, or 379aa–1 of this title with respect to any such article, or has not allowed access to records described in such section 364a, 379aa, or 379aa–1 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 1498(a)(1) of title 19) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regula-

[1] So in original. Probably should be preceded by a comma.

tions shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee. Neither clause (2) nor clause (5) of the third sentence of this subsection shall be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

(b) Disposition of refused articles

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that (1) an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this chapter or rendered other than a food, drug, device, or cosmetic, or (2) with respect to an article described in subsection (a) relating to the requirements of section 364a, 379aa, or 379aa–1 of this title, the responsible person (as defined in section 364, 379aa, or 379aa–1 of this title) can take action that would assure that the responsible person is in compliance with section 364a, 379aa, or 379aa–1 of this title, as the case may be, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant, or, with respect to clause (2), the responsible person, to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) Charges concerning refused articles

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) Reimportation

(1)(A) Except as provided in paragraph (2) and section 384 of this title, no drug subject to section 353(b) of this title or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

(B) Except as authorized by the Secretary in the case of a drug that appears on the drug shortage list under section 356e of this title or in the case of importation pursuant to section 384 of this title, no drug that is subject to section 353(b)(1) of this title may be imported into the United States for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States.

(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

(3)(A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 382 of this title, or with section 351(h) of the Public Health Service Act [42 U.S.C. 262(h)].

(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).

(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.

(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph.

(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 382 of this title, or with section 351(h) of the Public Health Service Act [42 U.S.C. 262(h)].

(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.

(4) The importation into the United States of blood, blood components, source plasma, or source leukocytes or of a component, accessory, or part thereof is not permitted pursuant to paragraph (3) unless the importation complies with section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] or the Secretary permits the importation under appropriate circumstances and conditions, as determined by the Secretary. The importation of tissue or a component or part of tissue is not permitted pursuant to paragraph (3) unless the importation complies with section 361 of the Public Health Service Act [42 U.S.C. 264].

(e) Exports

(1) A food, drug, device, tobacco product or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter, and a tobacco product intended for export shall not be deemed to be in violation of section 387f(e), 387g, 387k, or 387t(a) of this title, if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

(2) Paragraph (1) does not apply to any device—

(A) which does not comply with an applicable requirement of section 360d or 360e of this title,

(B) which under section 360j(g) of this title is exempt from either such section, or

(C) which is a banned device under section 360f of this title,

unless, in addition to the requirements of paragraph (1), either (i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export or (ii) the device is eligible for export under section 382 of this title.

(3) A new animal drug that requires approval under section 360b of this title shall not be exported pursuant to paragraph (1) if such drug has been banned in the United States.

(4)(A) Any person who exports a food, drug, animal drug, or device may request that the Secretary—

(i) certify in writing that the exported food, drug, animal drug, or device meets the requirements of paragraph (1) or section 382 of this title; or

(ii) certify in writing that the food, drug, animal drug, or device being exported meets the applicable requirements of this chapter upon a showing that the food, drug or device meets the applicable requirements of this chapter.

The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification.

(B) If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed $175 for each certification. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(C) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.

(D) With regard to fees pursuant to subparagraph (B) in connection with written export certifications for food:

(i) Such fees shall be collected and available solely for the costs of the Food and Drug Administration associated with issuing such certifications.

(ii) Such fees may not be retained in an amount that exceeds such costs for the respective fiscal year.

(E)(i)(I) If the Secretary denies a request for certification under subparagraph (A)(ii) with respect to a device manufactured in an establishment (foreign or domestic) registered under section 360 of this title, the Secretary shall provide in writing to the person seeking such certification the basis for such denial, and specifically identify the finding upon which such denial is based.

(II) If the denial of a request as described in subclause (I) is based on grounds other than an injunction proceeding pursuant to section 332 of this title, seizure action pursuant to section 334 of this title, or a recall designated Class I or Class II pursuant to part 7, title 21, Code of Federal Regulations, and is based on the facility being out of compliance with part 820 of title 21, Code of Federal Regulations, the Secretary shall provide a substantive summary of the specific grounds for noncompliance identified by the Secretary.

(III) With respect to a device manufactured in an establishment that has received a report under section 374(b) of this title, the Secretary shall not deny a request for certification as described in subclause (I) with respect to a device based solely on the issuance of that report if the owner, operator, or agent in charge of such establishment has agreed to a plan of correction in response to such report.

(ii)(I) The Secretary shall provide a process for a person who is denied a certification as described in clause (i)(I) to request a review that conforms to the standards of section 360g–1(b) of this title.

(II) Notwithstanding any previous review conducted pursuant to subclause (I), a person who has been denied a certification as described in clause (i)(I) may at any time request a review in order to present new information relating to actions taken by such person to address the reasons identified by the Secretary for the denial of certification, including evidence that corrective actions are being or have been implemented to address grounds for noncompliance identified by the Secretary.

(III) Not later than 1 year after August 18, 2017, the Secretary shall issue guidance providing for a process to carry out this subparagraph. Not later than 1 year after the close of the comment period for such guidance, the Secretary shall issue final guidance.

(F)(i) This paragraph applies to requests for certification under this subparagraph of a device manufactured by a device establishment located outside of the United States that is registered under section 360 of this title, if the device is listed pursuant to section 360(j) of this title, the device has been cleared, approved, or is not required to submit a premarket report pursuant to subsection (*l*) or (m) of section 360 of this title, and the device is imported or offered for import into the United States.

(ii) The Secretary shall issue the certification as described in clause (iii) if the device or devices for which certification is requested under this subparagraph meet the applicable requirements of this chapter.

(iii)(I) A certification for a device described in clause (i) shall be subject to the fee described in subparagraph (B).

(II) Notwithstanding subparagraph (C), a certification for a device described in clause (i) shall address and include the same material information as a ''Certificate to Foreign Government'' and shall have a document title including the words ''Certificate to Foreign Government''.

(iv) The requirements and procedures of subparagraph (E) shall apply to a denial of a certification under this subparagraph.

(f) Labeling of exported drugs

(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 382 of this title) being exported in accordance with subsection (e) is being exported to a country that has different or additional labeling requirements or conditions for use and such country requires the drug to be labeled in accordance with those requirements or uses, such drug may be labeled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labeled in accordance with the requirements of this chapter.

(2) If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this chapter, the labeling must state that such conditions for use have not been approved under this chapter. A drug exported under section 382 of this title is exempt from this section.

(g) Warning notice of importation in violation of chapter

(1) With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the business of such importations, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of subsection (a) because the drug is or appears to be adulterated, misbranded, or in violation of section 355 of this title;

(ii) importation is in violation of subsection (a) because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of subsection (d)(1); or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying such determination by the Secretary, includ-

ing a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(2) For purposes of this section, the term ''warning notice'', with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this chapter.

(h) Protection against adulteration of food

(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this chapter.

(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 5304(e) of title 25).

(i) Testing for rapid detection of adulteration of food

(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) The Secretary shall annually 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 describing the progress made in research under paragraph (1), including progress regarding paragraph (2).

(j) Temporary holds at ports of entry

(1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this chapter in which the article involved is located, or is an official senior to such director.

(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that such article is being held under this subsection.

(k) Importation by debarred persons

(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 335a(b)(3) of this title, such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 335a(b)(3) of this title if such person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this chapter, as determined by the Secretary.

***(l)* Failure to register**

(1)[2] If an article of food is being imported or offered for import into the United States, and

[2] So in original. No par. (2) has been enacted.

such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 350d of this title (or for which a registration has been suspended under such section), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(m) Prior notice of imported food shipments

(1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; any country to which the article has been refused entry; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this chapter.

(B) This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(n) Labeling of food refused admission

(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: ''UNITED STATES: REFUSED ENTRY''.

(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this chapter.

***(o)* Registration statement**

If an article that is a device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 360(i) of this title of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize

the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(p) Report

(1) Not later than 36 months after June 22, 2009, and annually thereafter, the Secretary shall 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 regarding—

(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this chapter;

(B) the public health implications of such exports, including any evidence of a negative public health impact; and

(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.

(q) Certifications concerning imported foods

(1) In general

The Secretary may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that the article of food complies with applicable requirements of this chapter. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary may specify.

(2) Factors to be considered in requiring certification

The Secretary shall base the determination that an article of food is required to have a certification described in paragraph (1) on the risk of the food, including—

(A) known safety risks associated with the food;

(B) known food safety risks associated with the country, territory, or region of origin of the food;

(C) a finding by the Secretary, supported by scientific, risk-based evidence, that—

(i) the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this chapter; and

(ii) the certification would assist the Secretary in determining whether to refuse or admit the article of food under subsection (a); and

(D) information submitted to the Secretary in accordance with the process established in paragraph (7).

(3) Certifying entities

For purposes of paragraph (1), entities that shall provide the certification or assurances described in such paragraph are—

(A) an agency or a representative of the government of the country from which the article of food at issue originated, as designated by the Secretary; or

(B) such other persons or entities accredited pursuant to section 384d of this title to provide such certification or assurance.

(4) Renewal and refusal of certifications

The Secretary may—

(A) require that any certification or other assurance provided by an entity specified in paragraph (2) be renewed by such entity at such times as the Secretary determines appropriate; and

(B) refuse to accept any certification or assurance if the Secretary determines that such certification or assurance is not valid or reliable.

(5) Electronic submission

The Secretary shall provide for the electronic submission of certifications under this subsection.

(6) False statements

Any statement or representation made by an entity described in paragraph (2) to the Secretary shall be subject to section 1001 of title 18.

(7) Assessment of food safety programs, systems, and standards

If the Secretary determines that the food safety programs, systems, and standards in a foreign region, country, or territory are inadequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this chapter, the Secretary shall, to the extent practicable, identify such inadequacies and establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to such food safety program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this chapter.

(r) Standards for admission of imported drugs

(1) The Secretary may require, pursuant to the regulations promulgated under paragraph (4)(A), as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this chapter.

(2) The information described under paragraph (1) may include—

(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

(B) facility information, such as proof of registration and the unique facility identifier;

(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

(A) through representation by a foreign government, if an inspection is conducted by a foreign government using standards and practices as determined appropriate by the Secretary;

(B) through representation by a foreign government or an agency of a foreign government recognized under section 384e of this title; or

(C) other appropriate documentation or evidence as described by the Secretary.

(4)(A) Not later than 18 months after July 9, 2012, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under 355(i)[3] of this title.

(B) In promulgating the regulations under subparagraph (A), the Secretary—

(i) may, as appropriate, take into account differences among importers and types of imports, and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections; and

(ii) shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).

(s) Registration of commercial importers

(1) Registration

The Secretary shall require a commercial importer of drugs—

(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

(B) subject to paragraph (4), to submit, at the time of registration, a unique identifier for the principal place of business for which the importer is required to register under this subsection.

(2) Regulations

(A) In general

The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the requirements of this chapter and the Public Health Service Act [42 U.S.C. 201 et seq.].

(B) Procedure

In promulgating a regulation under subparagraph (A), the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

(iii) publish the final regulation not less than 30 days before the regulation's effective date.

(C) Restrictions

Notwithstanding any other provision of Federal law, in implementing this subsection, the Secretary shall only promulgate regulations as described in subparagraph (B).

(D) Effective date

In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.

(3) Discontinuance of registration

The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

(4) Unique facility identifier

The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(5) Exemptions

The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection.

[3] So in original. Probably should be preceded by ''section''.

(t) Single source pattern of imported illegal drugs

If the Secretary determines that a person subject to debarment as a result of engaging in a pattern of importing or offering for import controlled substances or drugs as described in section 335a(b)(3)(D) of this title, and such pattern is identified by the Secretary as being offered for import from the same manufacturer, distributor, or importer, the Secretary may by order determine all drugs being offered for import from such person as adulterated or misbranded, unless such person can provide evidence otherwise.

(u) Illicit articles containing active pharmaceutical ingredients

(1) In general

For purposes of this section, an article that is being imported or offered for import into the United States may be treated by the Secretary as a drug if the article—

(A) is not—

(i) accompanied by an electronic import entry for such article submitted using an authorized electronic data interchange system; and

(ii) designated in such a system as an article regulated by the Secretary (which may include regulation as a drug, a device, a dietary supplement, or other product that is regulated under this chapter); and

(B) is an ingredient that presents significant public health concern and is, or contains—

(i) an active ingredient in a drug—

(I) that is approved under section 355 of this title or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262]; or

(II) for which—

(aa) an investigational use exemption has been authorized under section 355(i) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)]; and

(bb) a substantial clinical investigation has been instituted, and such investigation has been made public; or

(ii) a substance that has a chemical structure that is substantially similar to the chemical structure of an active ingredient in a drug or biological product described in subclause (I) or (II) of clause (i).

(2) Effect

This subsection shall not be construed to bear upon any determination of whether an article is a drug within the meaning of section 321(g) of this title, other than for the purposes described in paragraph (1).

(June 25, 1938, ch. 675, §801, 52 Stat. 1058; Oct. 18, 1949, ch. 696, §§1–3, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 90–399, §106, July 13, 1968, 82 Stat. 353; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 100–293, §3, Apr. 22, 1988, 102 Stat. 96; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–353, §5, Aug. 26, 1992, 106 Stat. 943; Pub. L. 103–80, §3(cc), (dd)(1), Aug. 13, 1993, 107 Stat. 778, 779; Pub. L. 104–134, title II, §2102(a)–(c), Apr. 26, 1996, 110 Stat. 1321–313, 1321–314; Pub. L. 104–180, title VI, §603(a), (b), Aug. 6, 1996, 110 Stat. 1594, 1595; Pub. L. 105–115, title I, §125(a)(2)(D), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 106–387, §1(a) [title VII, §§745(c)(1), 746(c)], Oct. 28, 2000, 114 Stat. 1549, 1549A–36, 1549A–40; Pub. L. 107–188, title III, §§302(a)–(d), 303(c), 304(e), 305(c), 307(a), 308(a), 321(b)(1), 322(a), June 12, 2002, 116 Stat. 662, 663, 665, 667, 668, 670, 672, 676; Pub. L. 109–462, §5(a), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, §912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(*l*), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title I, §§102(b)(3), 107(b), title II, §204(j)(2), title III, §§301(c), 303(a)–(c), 304(a), Jan. 4, 2011, 124 Stat. 3889, 3910, 3937, 3955–3957; Pub. L. 112–144, title VII, §§708(a), (b), 713, 714(b), July 9, 2012, 126 Stat. 1068, 1072, 1073; Pub. L. 114–255, div. A, title III, §3101(a)(2)(W)(i), Dec. 13, 2016, 130 Stat. 1155; Pub. L. 115–52, title VI, §604(a), title VII, §704, Aug. 18, 2017, 131 Stat. 1048, 1056; Pub. L. 115–271, title III, §§3012(c), 3013, 3022(c), (d), Oct. 24, 2018, 132 Stat. 3936, 3939, 3940; Pub. L. 116–136, div. A, title III, §3856(a), Mar. 27, 2020, 134 Stat. 458; Pub. L. 116–304, §2(a), Jan. 5, 2021, 134 Stat. 4915; Pub. L. 117–328, div. FF, title III, §§3304, 3503(a)(4)(C), (D), Dec. 29, 2022, 136 Stat. 5832, 5858.)

Editorial Notes

REFERENCES IN TEXT

The Controlled Substances Import and Export Act, referred to in subsec. (a), is title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, which is classified principally to subchapter II (§951 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 951 of this title and Tables.

The Federal Meat Inspection Act, referred to in subsec. (m)(3)(B), is titles I to V of act Mar. 4, 1907, ch. 2907, as added Pub. L. 90–201, Dec. 15, 1967, 81 Stat. 584, and Pub. L. 110–246, title XI, §11015(a), June 18, 2008, 122 Stat. 2124, which are classified generally to subchapters I to IV–A (§601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

The Poultry Products Inspection Act, referred to in subsec. (m)(3)(B), is Pub. L. 85–172, Aug. 28, 1957, 71 Stat. 441, which is classified generally to chapter 10 (§451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables.

The Egg Products Inspection Act, referred to in subsec. (m)(3)(B), is Pub. L. 91–597, Dec. 29, 1970, 84 Stat. 1620, which is classified principally to chapter 15 (§1031 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables.

The Public Health Service Act, referred to in subsec. (s)(2)(A), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §3503(a)(4)(C), substituted ''under section 364a, 379aa, or 379aa–1 of this title'' for ''under section 379aa or 379aa–1 of this title'', ''defined in section 364, 379aa, or 379aa–1 of this title'' for ''defined in such section 379aa or 379aa–1 of this

title'', ''of such section 364a, 379aa, or 379aa–1 of this title'' for ''of such section 379aa or 379aa–1 of this title'', and ''described in such section 364a, 379aa, or 379aa–1 of this title'' for ''described in such section 379aa or 379aa–1 of this title''.

Subsec. (b). Pub. L. 117–328, § 3503(a)(4)(D), substituted ''requirements of section 364a, 379aa, or 379aa–1 of this title'' for ''requirements of sections 379aa or 379aa–1 of this title,'', ''as defined in section 364, 379aa, or 379aa–1 of this title'' for ''defined in section 379aa or 379aa–1 of this title'', and ''with section 364a, 379aa, or 379aa–1 of this title'' for ''with section 379aa or 379aa–1 of this title''.

Subsec. (e)(4)(E)(iii). Pub. L. 117–328, § 3304(1), struck out cl. (iii) which applied to requests for certification on behalf of any device establishment registered under section 360 of this title, whether the establishment is located inside or outside of the United States, and regardless of whether such devices are to be exported from the United States.

Subsec. (e)(4)(F). Pub. L. 117–328, § 3304(2), added subpar. (F).

2021—Subsec. (a). Pub. L. 116–304 inserted ''or counterfeit device'' after ''counterfeit drug'' in fourth sentence, and substituted ''The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 1498(a)(1) of title 19) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).'' for ''The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 1498(a)(1) of title 19) and was not brought into compliance as described under subsection (b).. The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug under the sixth sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).''

2020—Subsec. (e)(4)(E)(iii). Pub. L. 116–136 substituted ''paragraph'' for ''subparagraph'' in subcls. (I) and (II).

2018—Subsec. (a). Pub. L. 115–271, § 3022(c)(2), (3), inserted ''If it appears from the examination of such samples or otherwise that the article is a counterfeit drug, such article shall be refused admission.'' after third sentence, and substituted ''Neither clause (2) nor clause (5) of the third sentence of this subsection shall be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under the Controlled Substances Import and Export Act.'' for ''Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.''

Pub. L. 115–271, § 3022(c)(1), which directed substitution of ''or (5) such article is being imported or offered for import in violation of section 331(cc) of this title, then any such article described in any of clauses (1) through (5) shall be refused admission'' for '', then such article shall be refused admission'', was executed by making the substitution only in the third sentence, to reflect the probable intent of Congress.

Pub. L. 115–271, § 3012(c), inserted '', or is a controlled substance subject to an order under section 360bbb–8d of this title'' before ''or (4)'' in third sentence.

Subsec. (t). Pub. L. 115–271, § 3013, added subsec. (t).

Subsec. (u). Pub. L. 115–271, § 3022(d), added subsec. (u).

2017—Subsec. (d)(1). Pub. L. 115–52, § 604(a), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (e)(4)(C), (D). Pub. L. 115–52, § 704(2), realigned margins.

Subsec. (e)(4)(E). Pub. L. 115–52, § 704(1), added subpar. (E).

2016—Subsec. (s)(2)(D). Pub. L. 114–255 added subpar. (D).

2012—Subsec. (a). Pub. L. 112–144, § 708(b), inserted ''The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug under the sixth sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee.'' after ''described under subsection (b)..''

Pub. L. 112–144, § 708(a), inserted '', except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 1498(a)(1) of title 19 and was not brought into compliance as described under subsection (b).'' after ''pursuant to such regulations''.

Subsec. (*o*). Pub. L. 112–144, § 713(1), struck out ''drug or'' after ''If an article that is a''.

Subsec. (r). Pub. L. 112–144, § 713(2), added subsec. (r).

Subsec. (s). Pub. L. 112–144, § 714(b), added subsec. (s).

2011—Subsec. (a). Pub. L. 111–353, § 301(c), inserted ''or the importer (as defined in section 384a of this title) is

in violation of such section 384a of this title'' after ''or in violation of section 355 of this title''.

Pub. L. 111–353, §§ 204(j)(2), 303(a), inserted ''or (4) the recordkeeping requirements under section 2223 of this title (other than the requirements under subsection (f) of such section) have not been complied with regarding such article,'' in the third sentence before ''then such article shall be refused admission'' and inserted after the third sentence ''With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this chapter, then such article shall be refused admission.''

Subsec. (b). Pub. L. 111–353, § 303(c), substituted ''with respect to an article described in subsection (a) relating to the requirements of sections 379aa or 379aa–1 of this title,'' for ''with respect to an article included within the provision of the fourth sentence of subsection (a)'' in second sentence.

Subsec. (e)(4)(A). Pub. L. 111–353, § 107(b)(1)(A), substituted ''a food, drug'' for ''a drug'' in introductory provisions.

Subsec. (e)(4)(A)(i). Pub. L. 111–353, § 107(b)(1)(B), substituted ''exported food, drug'' for ''exported drug''.

Subsec. (e)(4)(A)(ii). Pub. L. 111–353, § 107(b)(1)(C), substituted ''the food, drug'' for ''the drug'' in two places.

Subsec. (e)(4)(C). Pub. L. 111–353, § 107(b)(2), added subpar. (C).

Subsec. (e)(4)(D). Pub. L. 111–353, § 107(b)(3), added subpar. (D).

Subsec. (*l*). Pub. L. 111–353, § 102(b)(3), inserted ''(or for which a registration has been suspended under such section)'' after ''section 350d of this title''.

Subsec. (m)(1). Pub. L. 111–353, § 304(a), inserted ''any country to which the article has been refused entry;'' after ''the country from which the article is shipped;''.

Subsec. (q). Pub. L. 111–353, § 303(b), added subsec. (q).

2009—Subsec. (a). Pub. L. 111–31, § 103(*l*)(1)(C), which directed substitution of ''drugs, devices, or tobacco products'' for ''drugs or devices'' wherever appearing, was executed by making the substitution for ''drugs and devices'' in two places in second sentence, to reflect the probable intent of Congress.

Pub. L. 111–31, § 103(*l*)(1)(A), (B), inserted ''tobacco products,'' after ''devices,'' in first sentence and ''or section 387e(h)'' after ''section 360'' in second sentence.

Subsec. (e)(1). Pub. L. 111–31, § 103(*l*)(2), in introductory provisions, inserted ''tobacco product'' after ''drug, device,'' and '', and a tobacco product intended for export shall not be deemed to be in violation of section 387f(e), 387g, 387k, or 387t(a) of this title,'' after ''chapter''.

Subsec. (p). Pub. L. 111–31, § 103(*l*)(3), added subsec. (p).

2007—Subsec. (a). Pub. L. 110–85 substituted ''is adulterated, misbranded, or in violation of section 355 of this title, or prohibited from introduction or delivery for introduction into interstate commerce under section 331(*ll*) of this title,'' for ''is adulterated, misbranded, or in violation of section 355 of this title,''.

2006—Subsec. (a). Pub. L. 109–462, § 5(a)(1), inserted after third sentence ''If such article is subject to a requirement under section 379aa or 379aa–1 of this title and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 379aa or 379aa–1 of this title) has not complied with a requirement of such section 379aa or 379aa–1 of this title with respect to any such article, or has not allowed access to records described in such section 379aa or 379aa–1 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section.''

Subsec. (b). Pub. L. 109–462, § 5(a)(2), in second sentence, inserted ''(1)'' before ''an article included'', ''or (2) with respect to an article included within the provision of the fourth sentence of subsection (a), the responsible person (as defined in section 379aa or 379aa–1 of this title) can take action that would assure that the responsible person is in compliance with section 379aa or 379aa–1 of this title, as the case may be,'' before ''final determination'', and '', or, with respect to clause (2), the responsible person,'' before ''to perform''.

2002—Subsec. (d)(3). Pub. L. 107–188, § 322(a), amended par. (3) generally. Prior to amendment, par. (3) read as follows: ''No component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) of this section if—

''(A) the importer of such article of a drug or device or importer of the food additive, color additive, or dietary supplement submits a statement to the Secretary, at the time of initial importation, that such article of a drug or device, food additive, color additive, or dietary supplement is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by such owner or consignee from the United States in accordance with subsection (e) of this section or section 382 of this title or section 262(h) of title 42;

''(B) the initial owner or consignee responsible for such imported article maintains records that identify the use of such imported article and upon request of the Secretary submits a report that provides an accounting of the exportation or the disposition of the imported article, including portions that have been destroyed, and the manner in which such person complied with the requirements of this paragraph; and

''(C) any imported component, part, article, or accessory of a drug or device and any food additive, color additive, or dietary supplement not incorporated or further processed as described in subparagraph (A) is destroyed or exported by the owner or consignee.''

Subsec. (h). Pub. L. 107–188, § 302(a)–(c), added subsec. (h).

Subsec. (i). Pub. L. 107–188, § 302(d), added subsec. (i).

Subsec. (j). Pub. L. 107–188, § 303(c), added subsec. (j).

Subsec. (k). Pub. L. 107–188, § 304(e), added subsec. (k).

Subsec. (*l*). Pub. L. 107–188, § 305(c), added subsec. (*l*).

Subsec. (m). Pub. L. 107–188, § 307(a), added subsec. (m).

Subsec. (n). Pub. L. 107–188, § 308(a), added subsec. (n).

Subsec. (*o*). Pub. L. 107–188, § 321(b)(1), added subsec. (*o*).

2000—Subsec. (d)(1). Pub. L. 106–387, § 1(a) [title VII, § 745(c)(1)], inserted ''and section 384 of this title'' after ''paragraph (2)''.

Subsec. (g). Pub. L. 106–387, § 1(a) [title VII, § 746(c)], added subsec. (g).

1997—Subsec. (d)(1). Pub. L. 105–115 inserted ''or composed wholly or partly of insulin'' after ''353(b) of this title''.

1996—Subsec. (d)(3). Pub. L. 104–180, § 603(a), substituted ''accessory of a device, or other article of device requiring further processing, which is ready'' for ''accessory of a device which is ready'' in introductory provisions, inserted ''further processed by the initial owner or consignee, or'' after ''is intended to be'' in subpar. (A), and inserted ''article,'' after ''part,'' and ''or further processed'' after ''incorporated'' in subpar. (C).

Pub. L. 104–134, § 2102(a)(1), added par. (3)

Subsec. (d)(4). Pub. L. 104–134, § 2102(a)(1), added par. (4).

Subsec. (e)(1). Pub. L. 104–134, § 2102(b)(1), struck out concluding provisions which read as follows: ''This paragraph does not authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 360b of this title.''

Subsec. (e)(2). Pub. L. 104–134, § 2102(b)(2), in concluding provisions, substituted ''either (i) the Secretary'' for ''the Secretary'' and added cl. (ii).

Subsec. (e)(3), (4). Pub. L. 104–134, § 2102(b)(3), added pars. (3) and (4).

Subsec. (f). Pub. L. 104–180, § 603(b), inserted ''(other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 382 of this title)'' after ''If a drug'' in par. (1) and ''A drug exported under section 382 of this title is exempt from this section.'' at end of par. (2).

Pub. L. 104–134, § 2102(c), added subsec. (f).

1993—Subsec. (a). Pub. L. 103–80, § 3(dd)(1), substituted ''Health and Human Services'' for ''Agriculture'' after ''Secretary of'' in two places in first sentence.

Subsec. (b). Pub. L. 103–80, § 3(cc), substituted ''Secretary of Health and Human Services'' for ''Administrator'' after ''If it appears to the'', ''Secretary'' for ''Administrator'' after ''provisions of this subsection, the'', ''Secretary's'' for ''Administrator's'' after ''as may be specified in the'', ''Department of Health and Human Services'' for ''Federal Security Agency'', and ''Secretary'' for ''Administrator'' after ''designated by the''.

1992—Subsecs. (a), (b). Pub. L. 102–300, which directed the substitution of ''Health and Human Services'' for ''Health, Education, and Welfare'' wherever appearing, was executed in second sentence of subsec. (a), but could not be executed in first sentence of subsec. (a) or in subsec. (b) because such words did not appear. See 1993 Amendment note above and Transfer of Functions note below.

Subsec. (d)(1). Pub. L. 102–353 substituted ''manufacturer of'' for ''person who manufactured''.

1988—Subsecs. (d), (e). Pub. L. 100–293 added subsec. (d) and redesignated former subsec. (d) as (e).

1976—Subsec. (a). Pub. L. 94–295, §§ 3(f)(2), 4(b)(3), expanded provisions requiring the Secretary of Health, Education, and Welfare to request that the Secretary of the Treasury deliver to the Secretary of Health, Education, and Welfare items imported or offered for import into the United States that were manufactured, prepared, propagated, compounded, or processed in nonregistered establishments by extending the provisions to include devices imported or offered for import, and, in cl. (1), inserted reference to devices which were manufactured, packed, stored, or installed using methods, facilities, or controls not conforming to the requirements of section 360j(f) of this title.

Subsec. (d). Pub. L. 94–295, § 3(f)(1), designated existing provisions as par. (1) and added par. (2).

1970—Subsec. (a). Pub. L. 91–513 substituted ''Clause (2) of the third sentence of this paragraph'' for ''This paragraph'' and ''the Controlled Substances Import and Export Act'' for ''section 173 of this title'' in last sentence.

1968—Subsec. (d). Pub. L. 90–399 provided that nothing in subsec. (d) shall authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 360b of this title.

1962—Subsec. (a). Pub. L. 87–781 inserted provisions requiring the Secretary of Health, Education, and Welfare to furnish the Secretary of the Treasury a list of establishments registered under section 360(i) of this title, and to request that samples of any drugs from any establishments not so registered be delivered to the Secretary of Health, Education, and Welfare, with notice of delivery to the consignee who may appear before the Secretary to testify.

1949—Subsec. (a). Act Oct. 18, 1949, § 1, inserted before period at end of second sentence '', except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury within ninety days of the notice of such refusal or within such additional time as may be permitted pursuant to such regulations''.

Subsec. (b). Act Oct. 18, 1949, § 2, provided for express statutory authority for the long-standing administrative practice of releasing imported articles that do not comply with the requirements of the law so that they may be relabeled or given appropriate treatment to bring them into compliance.

Subsec. (c). Act Oct. 18, 1949, § 3, charged all costs, including salaries and travel and subsistence expenses of officers and employees, against importers.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by section 3503(a)(4)(C), (D) of Pub. L. 117–328 effective on the date that is 1 year after Dec. 29, 2022, see section 3503(b)(1) of Pub. L. 117–328, set out as a note under section 331 of this title.

EFFECTIVE DATE OF 2012 AMENDMENT; APPLICABILITY

Pub. L. 112–144, title VII, § 708(c), July 9, 2012, 126 Stat. 1069, provided that: ''The amendment made by subsection (a) [amending this section] shall apply beginning on the effective date of the regulations promulgated pursuant to the amendment made by subsection (b) [amending this section].''

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 301(c) of Pub. L. 111–353 effective 2 years after Jan. 4, 2011, see section 301(d) of Pub. L. 111–353, set out as a note under section 331 of this title.

Pub. L. 111–353, title III, § 304(c), Jan. 4, 2011, 124 Stat. 3958, provided that: ''The amendment made by this section [amending this section] shall take effect 180 days after the date of enactment of this Act [Jan. 4, 2011].''

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–462, § 5(b), Dec. 22, 2006, 120 Stat. 3476, provided that: ''The amendments made by this section [amending this section] shall take effect 1 year after the date of enactment of this Act [Dec. 22, 2006].''

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by section 321(b)(1) of Pub. L. 107–188 effective upon the expiration of the 180-day period beginning June 12, 2002, see section 321(c) of Pub. L. 107–188, set out as a note under section 331 of this title.

Amendment by section 322(a) of Pub. L. 107–188 effective upon the expiration of the 90-day period beginning June 12, 2002, see section 322(c) of Pub. L. 107–188, set out as a note under section 331 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100–293, set out as a note under section 353 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (d) by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

REGULATIONS

Pub. L. 112–144, title VII, § 708(d), July 9, 2012, 126 Stat. 1069, provided that:

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [July 9, 2012], the Secretary of Health and Human Services shall adopt final regulations implementing the amendments made this section [amending this section].

''(2) PROCEDURE.—In promulgating a regulation implementing the amendments made by this section, the Secretary of Health and Human Services shall—

''(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall promulgate regulations implementing the amendments made by this section only as described in paragraph (2).''

Pub. L. 112–144, title VII, §714(d), July 9, 2012, 126 Stat. 1074, provided that, within 36 months after July 9, 2012, the Secretary of Homeland Security acting through U.S. Customs and Border Protection, was to promulgate regulations required to carry out subsection (s) of this section relating to registration of commercial importers and specified procedures for promulgating regulations and their effective date, prior to repeal by Pub. L. 114–255, div. A, title III, §3101(a)(2)(W)(ii), Dec. 13, 2016, 130 Stat. 1156.

Pub. L. 111–353, title III, §304(b), Jan. 4, 2011, 124 Stat. 3958, provided that: ''Not later than 120 days after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall issue an interim final rule amending subpart I of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section [amending this section].''

Pub. L. 107–188, title III, §307(c), June 12, 2002, 116 Stat. 672, provided that:

''(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services shall promulgate proposed and final regulations for the requirement of providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 381(m)] (as added by subsection (a) of this section). Such requirement of notification takes effect—

''(A) upon the effective date of such final regulations; or

''(B) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.

''(2) DEFAULT; MINIMUM PERIOD OF ADVANCE NOTICE.—If under paragraph (1) the requirement for providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 381(m)] takes effect without final regulations having been made effective, then for purposes of such requirement, the specified period of time that the notice is required to be made in advance of the time of the importation of the article of food involved or the offering of the food for import shall be not fewer than eight hours and not more than five days, which shall remain in effect until the final regulations are made effective.''

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizure or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotic and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

CONSTRUCTION; CONFIDENTIALITY

Nothing in amendment made by section 3503(a)(4)(C), (D) of Pub. L. 117–328 to be construed to authorize the disclosure of information that is prohibited from disclosure under section 331(j) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5, see section 3503(c)(2) of Pub. L. 117–328, set out as a note under section 364 of this title.

CONSTRUCTION OF 2011 AMENDMENT

Pub. L. 111–353, title III, §303(d), Jan. 4, 2011, 124 Stat. 3957, provided that: ''Nothing in the amendments made by this section [amending this section] shall limit the authority of the Secretary to conduct inspections of imported food or to take such other steps as the Secretary deems appropriate to determine the admissibility of imported food.''

Nothing in amendments by sections 107(b), 204(j)(2), 301(c), and 303(a)–(c) of Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, see section 2206 of this title.

Nothing in amendments by Pub. L. 111–353 to be construed 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 2251 and 2252 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 107–188

Pub. L. 107–188, title III, §308(c), June 12, 2002, 116 Stat. 673, provided that: ''With respect to articles of food that are imported or offered for import into the United States, nothing in this section [amending this section and section 343 of this title] shall be construed to limit the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law.''

TRANSFER OF FUNCTIONS

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

PORT SHOPPING

Pub. L. 111–353, title I, §115, Jan. 4, 2011, 124 Stat. 3922, as amended by Pub. L. 114–125, title VIII, §802(d)(2), Feb. 24, 2016, 130 Stat. 210, provided that: ''Until the date on which the Secretary promulgates a final rule that implements the amendments made by section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (Public Law 107–188) [amending this section and section 343 of this title], the Secretary shall notify the Secretary of Homeland Security of all instances in which the Secretary refuses to admit a food into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) so that the Secretary of Homeland Security, acting through the Commissioner of U.S. Customs and Border Protection, may prevent food refused admittance into the United States by a United States port of entry from being admitted by another United States port of entry, through the notification of other such United States ports of entry.''

[''Commissioner of U.S. Customs and Border Protection'' substituted for ''Commissioner of Customs and Border Protection'' in section 115 of Pub. L. 111–353, set out above, to reflect the probable intent of section 802(d)(2) of Pub. L. 114–125, set out as a note under section 211 of Title 6, Domestic Security, which provided that on or after Feb. 24, 2016, any reference to the ''Commissioner of Customs'' or the ''Commissioner of the Customs Service'' would be deemed to be a reference to the Commissioner of U.S. Customs and Border Protection.]

MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION

With respect to any time periods specified in an amendment by div. A of Pub. L. 111–31 that begin on June 22, 2009, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, with certain limitations, the calculation of such time periods shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary has collected fees under section

387s of this title, and the Secretary may extend or reduce the duration of one or more such time periods, except that no such period shall be extended for more than 90 days, see section 6 of Pub. L. 111–31, set out as a note under section 387 of this title.

STUDY AND REPORT ON TRADE IN PHARMACEUTICALS

Pub. L. 108–173, title XI, § 1123, Dec. 8, 2003, 117 Stat. 2469, provided that: ''The President's designees shall conduct a study and report on issues related to trade and pharmaceuticals.''

FINDINGS

Pub. L. 106–387, § 1(a) [title VII, § 746(b)], Oct. 28, 2000, 114 Stat. 1549, 1549A–40, provided that: ''The Congress finds as follows:

''(1) Patients and their families sometimes have reason to import into the United States drugs that have been approved by the Food and Drug Administration ('FDA').

''(2) There have been circumstances in which—

''(A) an individual seeking to import such a drug has received a notice from FDA that importing the drug violates or may violate the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]; and

''(B) the notice failed to inform the individual of the reasons underlying the decision to send the notice.

''(3) FDA should not send a warning notice regarding the importation of a drug without providing to the individual involved a statement of the underlying reasons for the notice.''

Executive Documents

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.

§ 382. Exports of certain unapproved products

(a) Drugs or devices intended for human or animal use which require approval or licensing

A drug or device—

(1) which, in the case of a drug—

(A)(i) requires approval by the Secretary under section 355 of this title before such drug may be introduced or delivered for introduction into interstate commerce; or

(ii) requires licensing by the Secretary under section 262 of title 42 or by the Secretary of Agriculture under the Act of March 4, 1913 [21 U.S.C. 151 et seq.] (known as the Virus-Serum Toxin Act) before it may be introduced or delivered for introduction into interstate commerce;

(B) does not have such approval or license; and

(C) is not exempt from such sections or Act; and

(2) which, in the case of a device—

(A) does not comply with an applicable requirement under section 360d or 360e of this title;

(B) under section 360j(g) of this title is exempt from either such section; or

(C) is a banned device under section 360f of this title, is adulterated, misbranded, and in violation of such sections or Act unless the export of the drug or device is, except as provided in subsection (f), authorized under subsection (b), (c), (d), or (e) or section 381(e)(2) of this title. If a drug or device described in paragraphs (1) and (2) may be exported under subsection (b) and if an application for such drug or device under section 355 or 360e of this title or section 262 of title 42 was disapproved, the Secretary shall notify the appropriate public health official of the country to which such drug will be exported of such disapproval.

(b) List of eligible countries for export; criteria for addition to list; direct export; petition for exemption

(1)(A) A drug or device described in subsection (a) may be exported to any country, if the drug or device complies with the laws of that country and has valid marketing authorization by the appropriate authority—

(i) in Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa; or

(ii) in the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if the drug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area.

(B) The Secretary may designate an additional country to be included in the list of countries described in clauses (i) and (ii) of subparagraph (A) if all of the following requirements are met in such country:

(i) Statutory or regulatory requirements which require the review of drugs and devices for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs and devices which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for—

(I) the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength; and

(II) the manufacture, preproduction design validation, packing, storage, and installation of a device are adequate to assure that the device will be safe and effective.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and devices and procedures to withdraw approval and remove drugs and devices found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs and devices must be in accordance with the approval of the drug or device.

(v) The valid marketing authorization system in such country or countries is equivalent