

FEDERAL FOOD, DRUG AND COSMETIC ACT

SUBCHAPTER VIII - IMPORTS AND EXPORTS

Sec. 801 (21 USC 381) - Exports and Imports

(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission.

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 360 of this title and shall request that if any drugs and devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs and devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that

- (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or
- (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or
- (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph 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.

(b) Disposition of refused articles

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that an article included within the provisions of clause (3) of subsection (a) of this section can, by re-labeling or other action, be brought into compliance with this chapter or rendered other than a food,

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drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant to perform such re-labeling 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 re-labeling 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 re-labeling 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) Re-importation

- (1) 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.
- (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:

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- (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 802, or with section 351(h) of the Public Health Service Act.
 - (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) Records. 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) Reports. 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 802, or with section 351(h) of the Public Health Service Act.

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- (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. [Note: Paragraph (d) (3) revised per Public Law 107-188 (Public Health Security and Bioterrorism Preparedness and Response Act of 2002) of June 12, 2002 and effective September 12, 2002]
- (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 262(a) of title 42 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 264 of title 42.
- (e) Exports**
- (1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter if it -
- (A) accords to the specifications of the foreign purchaser,
 - (B) is not in conflict with the laws of the country to which it is intended for export,
 - (C) is labeled on the outside of the shipping package that it is intended for export, and
 - (D) is not sold or offered for sale in domestic commerce.
- (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.

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- (4) (A) Any person who exports a drug, animal drug, or device may request that the Secretary -
- (i) certify in writing that the exported drug, animal drug, or device meets the requirements of paragraph (1) or section 382 of this title; or
 - (ii) certify in writing that the drug, animal drug, or device being exported meets the applicable requirements of this chapter upon a showing that the 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.

(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) of this section 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:

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- (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) of this section 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) of this section 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) of this section; 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, including 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.

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Sec. 802 (21 USC 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) of this section, authorized under subsection (b), (c), (d), or (e) of this section 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) of this section 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) of this section 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

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- (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, pre-production 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 to the systems in the countries described in clauses (i) and (ii) of subparagraph (A). The Secretary shall not delegate the authority granted under this subparagraph.
- (C) An appropriate country official, manufacturer, or exporter may request the Secretary to take action under subparagraph (B) to designate an additional country or countries to be added to the list of countries described in clauses

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- (i) and (ii) of subparagraph (A) by submitting documentation to the Secretary in support of such designation. Any person other than a country requesting such designation shall include, along with the request, a letter from the country indicating the desire of such country to be designated.
- (2) A drug described in subsection (a) of this section may be directly exported to a country which is not listed in clause (i) or (ii) of paragraph (1)(A) if -
- (A) the drug complies with the laws of that country and has valid marketing authorization by the responsible authority in that country; and
- (B) the Secretary determines that all of the following requirements are met in that country:
- (i) Statutory or regulatory requirements which require the review of drugs for safety and effectiveness by an entity of the government of such country and which authorize the approval of only those drugs which have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.
- (ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength.
- (iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective.
- (iv) Statutory or regulatory requirements that the labeling and promotion of drugs must be in accordance with the approval of the drug.
- (3) The exporter of a drug described in subsection (a) of this section which would not meet the conditions for approval under this chapter or conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A) may petition the Secretary for authorization to export such drug to a country which is not described in clause (i) or (ii) of paragraph (1)(A) or which is not described in paragraph (2). The Secretary shall permit such export if -
- (A) the person exporting the drug -
- (i) certifies that the drug would not meet the conditions for approval under this chapter or the conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A); and

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- (ii) provides the Secretary with credible scientific evidence, acceptable to the Secretary, that the drug would be safe and effective under the conditions of use in the country to which it is being exported; and
- (B) the appropriate health authority in the country to which the drug is being exported -
 - (i) requests approval of the export of the drug to such country;
 - (ii) certifies that the health authority understands that the drug is not approved under this chapter or in a country described in clause (i) or (ii) of paragraph (1)(A); and
 - (iii) concurs that the scientific evidence provided pursuant to subparagraph (A) is credible scientific evidence that the drug would be reasonably safe and effective in such country. The Secretary shall take action on a request for export of a drug under this paragraph within 60 days of receiving such request.

(c) Investigational use exemption

A drug or device intended for investigational use in any country described in clause (i) or (ii) of subsection (b)(1)(A) of this section may be exported in accordance with the laws of that country and shall be exempt from regulation under section 355(i) or 360j(g) of this title.

(d) Anticipation of market authorization

A drug or device intended for formulation, filling, packaging, labeling, or further processing in anticipation of market authorization in any country described in clause (i) or (ii) of subsection (b)(1)(A) of this section may be exported for use in accordance with the laws of that country.

(e) Diagnosis, prevention, or treatment of tropical disease

- (1) A drug or device which is used in the diagnosis, prevention, or treatment of a tropical disease or another disease not of significant prevalence in the United States and which does not otherwise qualify for export under this section shall, upon approval of an application, be permitted to be exported if the Secretary finds that the drug or device will not expose patients in such country to an unreasonable risk of illness or injury and the probable benefit to health from the use of the drug or device (under conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling of the drug or device) outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available drug or device treatment.

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- (2) The holder of an approved application for the export of a drug or device under this subsection shall report to the Secretary -
 - (A) the receipt of any credible information indicating that the drug or device is being or may have been exported from a country for which the Secretary made a finding under paragraph (1)(A) to a country for which the Secretary cannot make such a finding; and
 - (B) the receipt of any information indicating adverse reactions to such drug.
- (3) (A) If the Secretary determines that -
 - (i) a drug or device for which an application is approved under paragraph (1) does not continue to meet the requirements of such paragraph; or
 - (ii) the holder of an approved application under paragraph (1) has not made the report required by paragraph (2), the Secretary may, after providing the holder of the application an opportunity for an informal hearing, withdraw the approved application.
- (B) If the Secretary determines that the holder of an approved application under paragraph (1) or an importer is exporting a drug or device from the United States to an importer and such importer is exporting the drug or device to a country for which the Secretary cannot make a finding under paragraph (1) and such export presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug or device to such importer, provide the person exporting the drug or device from the United States prompt notice of the prohibition, and afford such person an opportunity for an expedited hearing.

(f) Prohibition of export of drug or device

A drug or device may not be exported under this section -

- (1) if the drug or device is not manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements or does not meet international standards as certified by an international standards organization recognized by the Secretary;
- (2) if the drug or device is adulterated under clause (1), (2)(A), or (3) of section 351(a) or subsection (c) or (d) of section 351 of this title;
- (3) if the requirements of subparagraphs (A) through (D) of section 381(e)(1) of this title have not been met;

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- (4) (A) if the drug or device is the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the probability of re-importation of the exported drug or device would present an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the drug or device; or
- (B) if the drug or device presents an imminent hazard to the public health of the country to which the drug or device would be exported;
- (5) if the labeling of the drug or device is not -
 - (A) in accordance with the requirements and conditions for use in -
 - (i) the country in which the drug or device received valid marketing authorization under subsection (b) of this section; and
 - (ii) the country to which the drug or device would be exported; and
 - (B) in the language and units of measurement of the country to which the drug or device would be exported or in the language designated by such country; or
- (6) if the drug or device is not promoted in accordance with the labeling requirements set forth in paragraph (5). In making a finding under paragraph (4)(B), (5), or (6) the Secretary shall consult with the appropriate public health official in the affected country.

(g) Notification of Secretary

The exporter of a drug or device exported under subsection (b)(1) of this section shall provide a simple notification to the Secretary identifying the drug or device when the exporter first begins to export such drug or device to any country listed in clause (i) or (ii) of subsection (b)(1)(A) of this section. When an exporter of a drug or device first begins to export a drug or device to a country which is not listed in clause (i) or (ii) of subsection (b)(1)(A) of this section, the exporter shall provide a simple notification to the Secretary identifying the drug or device and the country to which such drug or device is being exported. Any exporter of a drug or device shall maintain records of all drugs or devices exported and the countries to which they were exported. "(b)(1)(A)".

(h) References to Secretary and term "drug"

For purposes of this section -

- (1) a reference to the Secretary shall in the case of a biological product which is required to be licensed under the Act of March 4, 1913 (21 U.S.C. 151 et seq.) (37 Stat. 832-833) (commonly known as the Virus-Serum Toxin Act) be considered to be a reference to the Secretary of Agriculture, and

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- (2) the term "drug" includes drugs for human use as well as biologicals under section 262 of title 42 or the Act of March 4, 1913 (37 Stat. 832-833) (commonly known as the Virus-Serum Toxin Act).

(i) Exportation

Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 381(e)(1) of this title.

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Sec. 803 (21 USC 383) - Office of International Relations

(a) Establishment

There is established in the Department of Health and Human Services an Office of International Relations.

(b) Agreements with foreign countries

In carrying out the functions of the office under subsection (a) of this section, the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of -

- (1) good manufacturing practice regulations promulgated under section 360j(f) of this title, and
- (2) other regulations and testing protocols as the Secretary determines to be appropriate.

(c) Harmonizing regulatory requirements

- (1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this chapter.
- (2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.
- (3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.
- (4) The Secretary shall, not later than 180 days after November 21, 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.
- (5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 321(ff) of this title.

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Sec. 804 (21 USC 384) - Importation of Covered Products

(a) Regulations

The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products.

(b) Limitation

Regulations under subsection (a) of this section shall -

- (1) require that safeguards be in place to ensure that each covered product imported pursuant to such subsection complies with section 355 of this title (including with respect to being safe and effective for its intended use), with sections 351 and 352 of this title, and with other applicable requirements of this chapter;
- (2) require that an importer of a covered product pursuant to subsection (a) of this section comply with the applicable provisions of this section, including subsection (d) of this section; and
- (3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of such products.

(c) Records

Regulations under subsection (a) of this section shall require that records regarding the importation of covered products pursuant to such subsection be provided to and maintained by the Secretary for a period of time determined to be necessary by the Secretary.

(d) Importation

Regulations under subsection (a) of this section shall require an importer of a covered product pursuant to such subsection to provide to the Secretary the following information and records:

- (1) The name and amount of the active ingredient of such product and description of the dosage form.
- (2) The date that the product is shipped and the quantity of the product that is shipped, points of origin and destination for the product, the price paid for the product by the importer, and (once the product is distributed) the price for which such product is sold by the importer.
- (3) Documentation from the foreign seller specifying the original source of the product and the amount of each lot of the product originally received.

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- (4) The manufacturer's lot or control number of the product imported.
- (5) The name, address, and telephone number of the importer, including the professional license number of the importer, if any.
- (6) For a product that is coming directly from the first foreign recipient of the product from the manufacturer:
 - (A) Documentation demonstrating that such product came from such recipient and was received by the recipient from such manufacturer.
 - (B) Documentation of the amount of each lot of the product received by such recipient to demonstrate that the amount being imported into the United States is not more than the amount that was received by the recipient.
 - (C) In the case of the initial imported shipment, documentation demonstrating that each batch of such shipment was statistically sampled and tested for authenticity and degradation.
 - (D) In the case of all subsequent shipments from such recipient, documentation demonstrating that a statistically valid sample of such shipments was tested for authenticity and degradation.
 - (E) Certification from the importer or manufacturer of such product that the product is approved for marketing in the United States and meets all labeling requirements under this chapter.
- (7) For a product that is not coming directly from the first foreign recipient of the product from the manufacturer:
 - (A) Documentation demonstrating that each batch in all shipments offered for importation into the United States was statistically sampled and tested for authenticity and degradation.
 - (B) Certification from the importer or manufacturer of such product that the product is approved for marketing in the United States and meets all labeling requirements under this chapter.
- (8) Laboratory records, including complete data derived from all tests necessary to assure that the product is in compliance with established specifications and standards.
- (9) Documentation demonstrating that the testing required by paragraphs (6) through (8) was performed at a qualifying laboratory (as defined in subsection (k) of this section).
- (10) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

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e) Testing

Regulations under subsection (a) of this section -

- (1) shall require that testing referred to in paragraphs (6) through (8) of subsection (d) of this section be conducted by the importer of the covered product pursuant to subsection (a) of this section, or the manufacturer of the product;
- (2) shall require that if such tests are conducted by the importer, information needed to authenticate the product being tested, and to confirm that the labeling of such product complies with labeling requirements under this chapter, be supplied by the manufacturer of such product to the pharmacist or wholesaler, and shall require that such information be kept in strict confidence and used only for purposes of testing under this chapter; and
- (3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

(f) Country limitation

Regulations under subsection (a) of this section shall provide that covered products may be imported pursuant to such subsection only from a country, union, or economic area that is listed in subparagraph (A) of section 382(b)(1) of this title or designated by the Secretary, subject to such limitations as the Secretary determines to be appropriate to protect the public health.

(g) Suspension of importations

The Secretary shall require that importations of specific covered products or importations by specific importers pursuant to subsection (a) of this section be immediately suspended upon discovery of a pattern of importation of such products or by such importers that is counterfeit or in violation of any requirement pursuant to this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative covered products being imported pursuant to subsection (a) of this section.

(h) Prohibited agreements

No manufacturer of a covered product may enter into a contract or agreement that includes a provision to prevent the sale or distribution of covered products imported pursuant to subsection (a) of this section.

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(i) Studies; reports

(1) Study by Secretary

(A) In general: The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted pursuant to subsection (a) of this section, including consideration of the information received under subsection (d) of this section. In conducting such study, the Secretary or entity shall -

(i) evaluate the compliance of importers with regulations under subsection (a) of this section, and the number of shipments pursuant to such subsection, if any, that have been determined to be counterfeit, misbranded, or adulterated, and determine how such compliance contrasts with the number of shipments of prescription drugs transported within the United States that have been determined to be counterfeit, misbranded, or adulterated; and

(ii) consult with the United States Trade Representative and the Commissioner of Patents and Trademarks to evaluate the effect of importations pursuant to subsection (a) of this section on trade and patent rights under Federal law.

(B) Report: Not later than 2 years after the effective date of final regulations under subsection (a) of this section, the Secretary shall prepare and submit to the Congress a report describing the findings of the study under subparagraph (A).

(2) Study by General Accounting Office: The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of covered products sold to consumers at retail. Not later than 18 months after the effective date of final regulations under subsection (a) of this section, the Comptroller General shall prepare and submit to the Congress a report describing the findings of such study.

(j) Construction

Nothing in this section shall be construed to limit the statutory, regulatory, or enforcement authority of the Secretary relating to the importation of covered products, other than with respect to section 381(d)(1) of this title as provided in this section.

(k) Definitions

(1) Covered product

(A) In general: For purposes of this section, the term "covered product" means a prescription drug, except that such term does not include a controlled

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substance in schedule I, II, or III under section 812(c) of this title or a biological product as defined in section 262 of title 42.

- (B) Charitable contributions; parenteral drugs; Notwithstanding any other provision of this section, section 381(d)(1) of this title -
 - (i) continues to apply to a covered product donated or otherwise supplied for free by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; and
 - (ii) continues to apply to a covered product that is a parenteral drug the importation of which pursuant to subsection (a) of this section is determined by the Secretary to pose a threat to the public health.
- (2) Other terms. For purposes of this section:
 - (A) The term "importer" means a pharmacist or wholesaler.
 - (B) The term "pharmacist" means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.
 - (C) The term "prescription drug" means a drug subject to section 353(b) of this title.
 - (D) The term "qualifying laboratory" means a laboratory in the United States that has been approved by the Secretary for purposes of this section.
 - (E) The term "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the United States pursuant to section 353(e)(2)(A) of this title. Such term does not include a person authorized to import drugs under section 381(d)(1) of this title.

(l) Conditions

This section shall become effective only if the Secretary demonstrates to the Congress that the implementation of this section will -

- (1) pose no additional risk to the public's health and safety; and
- (2) result in a significant reduction in the cost of covered products to the American consumer.

(m) Sunset

Effective upon the expiration of the 5-year period beginning on the effective date of final regulations under subsection (a) of this section, this section ceases to have any legal effect.