

## GUIDANCE

Pub. L. 111-31, div. A, title I, §103(q)(1), (2), June 22, 2009, 123 Stat. 1838, 1839, as amended by Pub. L. 116-94, div. N, title I, §603(d)(1), Dec. 20, 2019, 133 Stat. 3124, provided that:

“(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance [see 76 F.R. 22905, effective Apr. 15, 2011]—

“(A) defining the term ‘repeated violation’, as used in section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) as amended by subsection (c), as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation and providing for civil penalties in accordance with paragraph (2);

“(B) providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check, such notice to be sent to the location specified on the retailer’s registration or to the retailer’s registered agent if the retailer has provided [sic] such agent information to the Food and Drug Administration prior to the violation;

“(C) providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer’s request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;

“(D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

“(E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to paragraph (2) within the time periods provided for in such paragraph;

“(F) providing that good faith reliance on the presentation of a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

“(i) adopting and enforcing a written policy against sales to minors;

“(ii) informing its employees of all applicable laws;

“(iii) establishing disciplinary sanctions for employee noncompliance; and

“(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device; and

“(G) providing for the Secretary, in determining whether to impose a no-tobacco-sale order and in determining whether to compromise, modify, or terminate such an order, to consider whether the retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including the steps listed in subparagraph (F).

“(2) PENALTIES FOR VIOLATIONS.—

“(A) IN GENERAL.—The amount of the civil penalty to be applied for violations of section 906(d)(5) [probably means section 906(d)(5) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 387f(d)(5)] or of restrictions promulgated under section 906(d) [21 U.S.C. 387f(d)], as described in paragraph (1), shall be as follows:

“(i) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed—

“(I) in the case of the first violation, \$0.00 together with the issuance of a warning letter to the retailer;

“(II) in the case of a second violation within a 12-month period, \$250;

“(III) in the case of a third violation within a 24-month period, \$500;

“(IV) in the case of a fourth violation within a 24-month period, \$2,000;

“(V) in the case of a fifth violation within a 36-month period, \$5,000; and

“(VI) in the case of a sixth or subsequent violation within a 48-month period, \$10,000 as determined by the Secretary on a case-by-case basis.

“(ii) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed—

“(I) in the case of the first violation, \$250;

“(II) in the case of a second violation within a 12-month period, \$500;

“(III) in the case of a third violation within a 24-month period, \$1,000;

“(IV) in the case of a fourth violation within a 24-month period, \$2,000;

“(V) in the case of a fifth violation within a 36-month period, \$5,000; and

“(VI) in the case of a sixth or subsequent violation within a 48-month period, \$10,000 as determined by the Secretary on a case-by-case basis.

“(B) TRAINING PROGRAM.—For purposes of subparagraph (A), the term ‘approved training program’ means a training program that complies with standards developed by the Food and Drug Administration for such programs.

“(C) CONSIDERATION OF STATE PENALTIES.—The Secretary shall coordinate with the States in enforcing the provisions of this Act [probably means div. A of Pub. L. 111-31, see Short Title of 2009 Amendment note set out under section 301 of this title and Tables for classifications] and, for purposes of mitigating a civil penalty to be applied for a violation by a retailer of section 906(d)(5) [21 U.S.C. 387f(d)(5)] or of any restriction promulgated under section 906(d) [21 U.S.C. 387f(d)], shall consider the amount of any penalties paid by the retailer to a State for the same violation.”

## CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment 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.

## ENFORCEMENT

Pub. L. 99-660, title I, §103, Nov. 14, 1986, 100 Stat. 3751, provided that: “For the fines authorized to be imposed under section 303 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333], see section 3623 of title 18, United States Code, for the period ending October 31, 1986 [probably should be October 31, 1987], and sections 3559 and 3571 of such title for the period beginning November 1, 1986 [probably should be November 1, 1987].”

**§ 333a. Repealed. Pub. L. 101-647, title XIX, § 1905, Nov. 29, 1990, 104 Stat. 4853**

Section, Pub. L. 100-690, title II, §2401, Nov. 18, 1988, 102 Stat. 4230, related to forfeiture and illegal trafficking in steroids or human growth hormones.

**§ 334. Seizure**

**(a) Grounds and jurisdiction**

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 331(II), 344, or 355 of this title, be introduced into interstate

commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, (D) Any adulterated or misbranded device, and (E) Any adulterated or misbranded tobacco product.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

(i) is misbranded under section 343(a)(2) of this title because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(1)(I) the food's advertising which resulted in the food being misbranded under section 343(a)(2) of this title was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

**(b) Procedure; multiplicity of pending proceedings**

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

**(c) Availability of samples of seized goods prior to trial**

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

**(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures**

(1) Any food, drug, device, tobacco product, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold. After entry of the de-

cree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter, under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 381(e) of this title can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6), section 351(a)(3), section 352(j), or section 361(a) or (d) of this title. Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 381(e)(1) of this title and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(e) of this title have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section 344 or 355 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

**(e) Costs**

When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

**(f) Removal of case for trial**

In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

**(g) Administrative restraint; detention orders**

(1) If during an inspection conducted under section 374 of this title of a facility or a vehicle, a device, drug, or tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device, drug, or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 332 of this title, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device, drug, or tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device, drug, or tobacco product during the period of its detention for the purpose of identifying the device, drug, or tobacco product as detained. Any person who would be entitled to claim a device, drug, or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of such device, drug, or tobacco product under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device, drug, or tobacco product subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

- (i) released by the Secretary, or
- (ii) the expiration of the detention period applicable to such order,

whichever occurs first.

(B) A device or drug subject to a detention order under paragraph (1) may be moved—

- (i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device or drug for the purpose of completing the work required to put it in such form.

**(h) Administrative detention of foods**

**(1) Detention authority**

**(A) In general**

An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this chapter conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.

**(B) Secretary's approval**

An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. 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.

**(2) Period of detention**

An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 332 of this title. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

**(3) Security of detained article**

An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 381(b) of this title does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

**(4) Appeal of detention order**

**(A) In general**

With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and

such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

**(B) Effect of instituting court action**

The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 332 of this title regarding the article of food involved.

**(i) Procedures for promulgating regulations**

**(1) In general**

In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes 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 regulation's effective date.

**(2) Restrictions**

Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (1).

(June 25, 1938, ch. 675, §304, 52 Stat. 1044; June 24, 1948, ch. 613, §2, 62 Stat. 582; Aug. 7, 1953, ch. 350, §3, 67 Stat. 477; Pub. L. 85-250, Aug. 31, 1957, 71 Stat. 567; Pub. L. 89-74, §6, July 15, 1965, 79 Stat. 232; Pub. L. 90-639, §4(b), Oct. 24, 1968, 82 Stat. 1362; Pub. L. 91-513, title II, §701(c), (d), Oct. 27, 1970, 84 Stat. 1281, 1282; Pub. L. 94-278, title V, §502(a)(2)(C), Apr. 22, 1976, 90 Stat. 411; Pub. L. 94-295, §§3(c), 7(a), May 28, 1976, 90 Stat. 576, 582; Pub. L. 102-300, §6(c), June 16, 1992, 106 Stat. 240; Pub. L. 103-80, §3(f), Aug. 13, 1993, 107 Stat. 775; Pub. L. 105-115, title IV, §418, Nov. 21, 1997, 111 Stat. 2379; Pub. L. 107-188, title III, §303(a), June 12, 2002, 116 Stat. 663; Pub. L. 110-85, title IX, §912(b)(1), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111-31, div. A, title I, §103(d), June 22, 2009, 123 Stat. 1836; Pub. L. 111-353, title II, §207(a), Jan. 4, 2011, 124 Stat. 3944; Pub. L. 112-144, title VII, §709(a), (b)(2), July 9, 2012, 126 Stat. 1069.)

AMENDMENTS

2012—Subsec. (g)(1). Pub. L. 112-144, §709(a)(1), inserted “, drug,” after “device” wherever appearing.

Subsec. (g)(2)(A). Pub. L. 112-144, §709(a)(2), inserted “, drug,” after “(B), a device”.

Subsec. (g)(2)(B). Pub. L. 112-144, §709(a)(3), inserted “or drug” after “device” in introductory provisions and in cl. (ii).

Subsec. (i). Pub. L. 112-144, §709(b)(2), added subsec. (i).

2011—Subsec. (h)(1)(A). Pub. L. 111-353 substituted “reason to believe” for “credible evidence or information indicating” and “is adulterated or misbranded” for “presents a threat of serious adverse health consequences or death to humans or animals”.

2009—Subsec. (a)(2)(E). Pub. L. 111-31, §103(d)(1), added cl. (E).

Subsec. (d)(1). Pub. L. 111-31, §103(d)(2), inserted “tobacco product,” after “device,” in first sentence.

Subsec. (g)(1). Pub. L. 111-31, §103(d)(3), inserted “or tobacco product” after “device” wherever appearing.

Subsec. (g)(2)(A). Pub. L. 111-31, §103(d)(4), inserted “or tobacco product” after “device” in introductory provisions.

2007—Subsec. (a)(1). Pub. L. 110-85 substituted “section 331(l), 344, or 355” for “section 344 or 355”.

2002—Subsec. (h). Pub. L. 107-188 added subsec. (h).

1997—Subsec. (d)(1). Pub. L. 105-115 substituted “subparagraphs (A) and (B) of section 381(e)(1) of this title” for “paragraphs (1) and (2) of section 381(e) of this title” and inserted “Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.” before “Any article condemned by reason”.

1993—Subsec. (a)(1). Pub. L. 103-80, §3(f)(1), substituted “found. No libel” for “found: *Provided, however, That no libel*”.

Subsec. (d)(1). Pub. L. 103-80, §3(f)(2), substituted “sold. After entry” for “sold: *Provided, That after entry*”, “met. The provisions of this sentence” for “met: *Provided, however, That the provisions of this sentence*”, “title. Where such exportation” for “title: *And provided further, That where such exportation*”, and “the preceding sentence shall not be applicable” for “the foregoing proviso shall not be applicable”.

1992—Subsec. (d)(1). Pub. L. 102-300 substituted “381(e)” for “381(d)” in three places and “paragraphs” for “clauses” before “(1) and (2) of section 381(e)”.

1976—Subsec. (a)(1). Pub. L. 94-295, §3(c)(1), struck out “device,” after “Any article of food, drug,”.

Subsec. (a)(2). Pub. L. 94-295, §3(c)(2), (3), added cl. (D) covering adulterated or misbranded devices.

Subsec. (a)(3). Pub. L. 94-278 added par. (3).

Subsec. (g). Pub. L. 94-295, §7(a), added subsec. (g).

1970—Subsec. (a)(2). Pub. L. 91-513, §701(c), struck out cls. (A) and (D) which dealt with depressant or stimulant drugs, struck out reference to depressant or stimulant drugs in cl. (C), and redesignated cls. (B), (C), and (E) as cls. (A), (B), and (C), respectively.

Subsec. (d)(3)(iii). Pub. L. 91-513, §701(d), struck out reference to depressant or stimulant drugs.

1968—Subsec. (a). Pub. L. 90-639 inserted references to the United States courts of Territories.

1965—Subsec. (a)(2). Pub. L. 89-74, §6(a), designated existing provisions as par. (1), redesignated cls. (1) and (2) of proviso as (A) and (B), and added par. (2).

Subsec. (b). Pub. L. 89-74, §6(b)(1), inserted “equipment, or other thing proceeded against” after “article” in first sentence.

Subsec. (d). Pub. L. 89-74, §6(b)(2), designated existing provisions as par. (1), redesignated cls. (1) and (2) of the second sentence thereof as (A) and (B), and added pars. (2) and (3).

1957—Subsec. (d). Pub. L. 85-250 permitted, under certain circumstances, reexportation of articles condemned at places other than original port of entry.

1953—Subsec. (c). Act Aug. 7, 1953, provided that a true copy of the analysis in any case shall be furnished the owner.

1948—Subsec. (a). Act June 24, 1948, inserted “or while held for sale (whether or not the first sale) after shipment in interstate commerce” to make this subsection coextensive with section 331(k) of this title.

#### EFFECTIVE DATE OF 2012 AMENDMENT

Pub. L. 112-144, title VII, §709(c), July 9, 2012, 126 Stat. 1070, provided that: “The amendments made by subsection (a) [amending this section] shall not take effect until the Secretary has issued a final regulation under subsection (b) [amending this section and enacting provisions set out as a note under this section].”

[Final regulation issued May 29, 2014, effective June 30, 2014. See 79 F.R. 30716.]

#### EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 111-353, title II, §207(c), Jan. 4, 2011, 124 Stat. 3944, 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 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

#### EFFECTIVE DATE OF 1976 AMENDMENT

Pub. L. 94-278, title V, §502(c), Apr. 22, 1976, 90 Stat. 413, provided that: “The amendments made by subsection (a) [amending this section and sections 321, 333, and 343 of this title] shall take effect 180 days after the date of the enactment of this Act [Apr. 22, 1976].”

#### EFFECTIVE DATE OF 1970 AMENDMENT

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

#### EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90-639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

#### EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-74 effective Feb. 1, 1966, see section 11 of Pub. L. 89-74, set out as a note under section 321 of this title.

#### REGULATIONS

Pub. L. 112-144, title VII, §709(b)(1), July 9, 2012, 126 Stat. 1069, provided that: “Not later than 2 years after the date of the enactment of this Act [July 9, 2012], the Secretary of Health and Human Services shall promulgate regulations in accordance with section 304(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 334(i)], as added by paragraph (2) of this subsection, to implement administrative detention authority with respect to drugs, as authorized by the amendments made by subsection (a) [amending this section]. Before promulgating such regulations, the Secretary shall consult with stakeholders, including manufacturers of drugs.”

Pub. L. 111-353, title II, §207(b), Jan. 4, 2011, 124 Stat. 3944, 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 K of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section [amending this section].”

#### SAVINGS PROVISION

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

#### CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment 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.

#### 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.

**§ 335. Hearing before report of criminal violation**

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

(June 25, 1938, ch. 675, § 305, 52 Stat. 1045.)

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

**§ 335a. Debarment, temporary denial of approval, and suspension**

**(a) Mandatory debarment; certain drug applications**

**(1) Corporations, partnerships, and associations**

If the Secretary finds that a person other than an individual has been convicted, after May 13, 1992, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

**(2) Individuals**

If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this chapter,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

**(b) Permissive debarment; certain drug applications; food imports**

**(1) In general**

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2) or (3), debar—

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application;

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application;

(C) a person from importing an article of food or offering such an article for import into the United States; or

(D) a person from importing or offering for import into the United States a drug.

**(2) Persons subject to permissive debarment; certain drug applications**

The following persons are subject to debarment under subparagraph (A) or (B) of paragraph (1):

**(A) Corporations, partnerships, and associations**

Any person other than an individual that the Secretary finds has been convicted—

(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before May 13, 1992), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

**(B) Individuals**

(i) Any individual whom the Secretary finds has been convicted of—

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this chapter, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of—

(I) a felony which is not described in subsection (a)(2) or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) or in clause (i) or (ii) for which a conviction was obtained, if