

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.)

AMENDMENTS

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). 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 ship-

ment in interstate commerce” to make this subsection coextensive with section 331(k) of this title.

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

Section 502(c) of Pub. L. 94-278 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. 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 at-

torney 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), 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, or

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

(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) of this section,

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) of this section,

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) of this section 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) of this section or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation 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.

(iv) Any high managerial agent whom the Secretary finds—