

Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387)."

1962—Subsec. (a). Pub. L. 87-781, §103(d), struck out "(e)," after "paragraphs".

Pub. L. 87-781, §201(c), struck out "(f)," after "paragraphs".

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by section 103(c) of Pub. L. 87-781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87-781, set out as a note under section 321 of this title.

Section 203 of title II of Pub. L. 87-781 provided that: "The amendments made by this title [amending this section and section 374 of this title and enacting provisions set out as notes under sections 321 and 374 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962]."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 333, 334, 360j of this title; title 42 section 1396r-8.

§ 333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section,¹ if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title,

shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample

¹ So in original. Words "of this section" probably should not appear.

shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than \$100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in viola-

tion of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than \$125,000.

(6) Notwithstanding subsection (a) of this section, any person who is a manufacturer or importer of a covered product pursuant to section 384(a) of this title and knowingly fails to comply with a requirement of section 384(e) of this title that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) nor 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food

No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 331 of this title involving misbranded food if the violation exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising.

(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [21 U.S.C. 801 et seq.] for the purposes of forfeiture under section 413 of such Act [21 U.S.C. 853].

(4) As used in this subsection the term "human growth hormone" means somatrem, somatotropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f) Redesignated (g)

(g) Violations related to devices

(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 374(g) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 360i(a) or 360j(f) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 360i(e) or 360i(f) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 342(a)(2)(B) of this title shall be subject to a civil money penalty of not more than \$50,000 in the case of an individual and \$250,000 in the case of any other person for such introduction or delivery, not to exceed \$500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 334 of this title or the injunction authorities of section 332 of this title with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 346a(g)(2)(B) of this title. The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.

(3)(A) A civil penalty under paragraph (1) or (2) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1) or (2). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(4) Any person who requested, in accordance with paragraph (3)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or

transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(5) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (4), or

(B) after a court in an action brought under paragraph (4) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (4) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(June 25, 1938, ch. 675, § 303, 52 Stat. 1043; Oct. 26, 1951, ch. 578, § 2, 65 Stat. 649; Pub. L. 86-618, title I, § 105(b), July 12, 1960, 74 Stat. 403; Pub. L. 89-74, § 7, 9(d), July 15, 1965, 79 Stat. 233, 235; Pub. L. 90-639, § 3, Oct. 24, 1968, 82 Stat. 1361; Pub. L. 91-513, title II, § 701(b), Oct. 27, 1970, 84 Stat. 1281; Pub. L. 94-278, title V, § 502(a)(2)(B), Apr. 22, 1976, 90 Stat. 411; Pub. L. 100-293, § 7(b), Apr. 22, 1988, 102 Stat. 99; Pub. L. 100-690, title II, § 2403, Nov. 18, 1988, 102 Stat. 4230; Pub. L. 101-629, § 17(a), Nov. 28, 1990, 104 Stat. 4526; Pub. L. 101-647, title XIX, § 1904, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 102-353, § 3, Aug. 26, 1992, 106 Stat. 941; Pub. L. 103-80, § 3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103-322, title XXXIII, § 330015, Sept. 13, 1994, 108 Stat. 2146; Pub. L. 104-170, title IV, § 407, Aug. 3, 1996, 110 Stat. 1535; Pub. L. 106-387, § 1(a) [title VII, § 745(d)(2)], Oct. 28, 2000, 114 Stat. 1549, 1549A-40; Pub. L. 107-250, title II, § 201(c), Oct. 26, 2002, 116 Stat. 1609.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (e)(3), is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, as amended, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2002—Subsec. (g)(1)(A). Pub. L. 107-250 inserted at end “For purposes of the preceding sentence, a person accredited under paragraph (2) of section 374(g) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices.”

2000—Subsec. (b)(6). Pub. L. 106-387 added par. (6).

1996—Subsec. (g)(2). Pub. L. 104-170, § 407(1), (2), added par. (2). Former par. (2) redesignated (3).

Subsec. (g)(3). Pub. L. 104-170, § 407(1), (3), redesignated par. (2) as (3) and substituted “paragraph (1) or (2)” for “paragraph (1)” in subpars. (A) and (C). Former par. (3) redesignated (4).

Subsec. (g)(4). Pub. L. 104-170, § 407(1), (4), redesignated par. (3) as (4) and substituted “paragraph (3)(A)” for “paragraph (2)(A)”. Former par. (4) redesignated (5).

Subsec. (g)(5). Pub. L. 104-170, § 407(1), (5), redesignated par. (4) as (5) and substituted “paragraph (4)” for “paragraph (3)” wherever appearing.

1994—Subsec. (e). Pub. L. 103-322 amended directory language of Pub. L. 101-647. See 1990 Amendment note below.

1993—Subsecs. (e) to (g). Pub. L. 103-80, which directed the amendment of this section by redesignating the second subsec. (e) and subsec. (f) as subsecs. (f) and (g), respectively, could only be executed by designating subsec. (f) as (g) because this section did not contain a second subsec. (e) subsequent to amendment of Pub. L. 101-647 by Pub. L. 103-322. See 1990 and 1994 amendment notes for subsec. (e) under this section.

1992—Subsec. (b)(1). Pub. L. 102-353, §3(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: “Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title because of an importation of a drug in violation of section 381(d)(1) of this title, because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, or the distribution of drugs in violation of section 353(e)(2)(A) of this title shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.”

Subsec. (b)(4)(A). Pub. L. 102-353, §3(b)(1), substituted “the institution of a criminal proceeding against, and conviction of,” for “the arrest and conviction of”.

Subsec. (b)(4)(B)(i). Pub. L. 102-353, §3(b)(1), (2), substituted “before the institution of a criminal proceeding against” for “before the arrest of” and “the institution of a criminal proceeding against, and conviction of,” for “the arrest and conviction of”.

Subsec. (b)(5). Pub. L. 102-353, §3(b)(3), substituted “the institution of a criminal proceeding against, and conviction of,” for “the arrest and conviction of”.

Subsec. (c). Pub. L. 102-353, §3(b)(4), substituted “subsection (a)(1) of this section” for “subsection (a) of this section”.

Subsec. (d). Pub. L. 102-353, §3(b)(4), (5), substituted “subsection (a)(1) of this section” for “subsection (a) of this section” and struck out “, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead” after “advertising”.

1990—Subsec. (e). Pub. L. 101-647, as amended by Pub. L. 103-322, amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows:

“(e)(1) Except as provided in paragraph (2), any person who distributes or possesses with the intent to distribute any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than three years or fined under title 18, or both.

“(2) Any person who distributes or possesses with the intent to distribute to an individual under 18 years of age, any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than six years or fined under title 18, or both.”

Subsec. (f). Pub. L. 101-629 added subsec. (f).

1988—Subsecs. (a), (b). Pub. L. 100-293 designated existing subsecs. (a) and (b) as pars. (1) and (2) of subsec. (a), substituted “paragraph (1)” for “subsection (a)” in par. (2), and added subsec. (b).

Subsec. (e). Pub. L. 100-690 added subsec. (e).

1976—Subsec. (d). Pub. L. 94-278 added subsec. (d).

1970—Subsec. (a). Pub. L. 91-513 struck out reference to subsec. (b) and transferred to subsec. (b) provisions covering second offenses and offenses committed with intent to defraud or mislead.

Subsec. (b). Pub. L. 91-513 inserted provisions covering second offenses and offenses committed with intent to defraud or mislead formerly set out in subsec. (a) and struck out provisions covering violations involving depressant and stimulant drugs. See section 801 et seq. of this title.

1968—Subsecs. (a), (b). Pub. L. 90-639 made a general revision in the penalties prescribed for offenses involving depressant or stimulant drugs, set a fine of not to exceed \$10,000 or imprisonment of not more than 5 years for offenses involving the unlawful manufacturing of, sale, or disposal of, or possession with intent to sell, a depressant or stimulant drug or involving counterfeit depressant or stimulant drugs, stiffened the penalties for unlawful sales or other disposals by persons over 18 to persons under 21, and set new penalties for possession of a depressant or stimulant drug for purposes other than sale or other disposal.

1965—Subsec. (a). Pub. L. 89-74, §7(a), inserted proviso limiting the penalties for depressant or stimulant drug violations to two years imprisonment or \$5,000 fine or both for first offense and to two years imprisonment or \$15,000 fine or both for subsequent offenses.

Subsec. (b). Pub. L. 89-74, §7(b), inserted parenthetical exception provision.

Subsec. (c)(5). Pub. L. 89-74, §9(d), added cl. (5).

1960—Subsec. (c)(3). Pub. L. 86-618 substituted “a color additive” for “a coal-tar color”, “the color additive” for “the coal-tar color” and “such color additive was” for “such color was”.

1951—Subsec. (c)(4). Act Oct. 26, 1951, added cl. (4).

EFFECTIVE DATE OF 1994 AMENDMENT

Section 330015 of Pub. L. 103-322 provided that the amendment made by that section is effective as of the date on which section 1904 of Pub. L. 101-647, which amended this section, took effect.

EFFECTIVE DATE OF 1990 AMENDMENT

Section 17(b) of Pub. L. 101-629 provided that:

“(b) EFFECTIVE DATE OF APPLICATION TO DEVICE USER FACILITIES.—

“(1) The Secretary of Health and Human Services shall conduct a study to determine whether there has been substantial compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)] by device user facilities (as defined in section 519(b)(5)(A) of such Act). The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act [Nov. 28, 1990].

“(2)(A) If upon the expiration of 48 months after the date of the enactment of this Act [Nov. 28, 1990] the Secretary has not made the report required by paragraph (1), section 303(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333(f)], as added by the amendment made by subsection (a), shall take effect with respect to device user facilities (as defined in section 519(b)(5)(A) of such Act). [Secretary of Health and Human Services had not made the report required by par. (1) on the expiration of 48 months after Nov. 28, 1990.]

“(B) If in the report under paragraph (1) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by a type of device user facility and if the Secretary does not make a determination under subparagraph (C) with respect to such type of facility, such section 303(f) shall not take effect with respect to such type of facility.

“(C) If the Secretary determines in the report under paragraph (1) that there is not substantial compliance with the requirements of such section 519(b) by a type of device user facility or if the Secretary makes such a determination after making the report under paragraph (1), such section 303(f) shall take effect with respect to such type of facility upon the effective date of the report.”

EFFECTIVE DATE OF 1988 AMENDMENT

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

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94-278, set out as a note under section 334 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

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

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment 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.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF 1951 AMENDMENT

Section 3 of act Oct. 26, 1951, provided that: "The provisions of this Act [amending this section and section 353 of this title] shall take effect six months after the date of its enactment [Oct. 26, 1951]."

SAVINGS PROVISION

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for 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.

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 note set out under section 41 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]."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360j, 859 of this title; title 15 section 1456.

§ 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 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, and (D) Any adulterated or misbranded device.

(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 es-