341, 350c, 350d, and 381 of this title], or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.''

PREEMPTION OF STATE LAWS

Pub. L. 114–114, §2(c), Dec. 28, 2015, 129 Stat. 3129, provided that: ''No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect restrictions with respect to the manufacture or introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing plastic microbeads (as defined in section 301(ddd) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)) that are not identical to the restrictions under such section 301(ddd) that have begun to apply under subsection (b) [set out as a note above].''

Executive Documents

TRANSFER OF FUNCTIONS

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

§ 332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown[1] to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

(June 25, 1938, ch. 675, §302, 52 Stat. 1043; Pub. L. 87–781, title I, §103(d), title II, §201(c), Oct. 10, 1962, 76 Stat. 784, 793; Pub. L. 103–80, §3(d), Aug. 13, 1993, 107 Stat. 775.)

Editorial Notes

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–80, §3(d)(1), struck out '', and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes', approved October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 381),'' after ''for cause shown''.

Subsec. (b). Pub. L. 103–80, §3(d)(2), struck out at end ''Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such 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''.

Statutory Notes and Related Subsidiaries

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.

Pub. L. 87–781, title II, §203, Oct. 10, 1962, 76 Stat. 793, 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].''

§ 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), 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)(1) 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 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

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

[1] So in original. Words ''of this section'' probably should not appear.

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 violation 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), any person who is a manufacturer or importer of a prescription drug under section 384(b) 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.

(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 351 of this title and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.

(8) Notwithstanding subsection (a), any person who violates section 331(i)(3) of this title by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug, or who violates section 331(fff)(3) of this title by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit device, shall be imprisoned for not more than 10 years or fined in accordance with title 18, 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; or (6) for having violated section 331(fff)(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 device being a counterfeit device, or for having violated section 331(fff)(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 device was a counterfeit device.

(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, somatropin, or an analogue of either of them.

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

(f) 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(g) 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 or any person who does not comply with a recall order under section 350*l* 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 (5)(A) shall not apply to any investigation under this paragraph.

(3)(A) Any person who violates section 331(jj) of this title shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

(B) If a violation of section 331(jj) of this title is not corrected within the 30-day period following notification under section 282(j)(5)(C)(ii)[2] of title 42, the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.

(4)(A) Any responsible person (as such term is used in section 355–1 of this title) that violates a requirement of section 355(*o*), 355(p), or 355–1 of this title shall be subject to a civil monetary penalty of—

(i) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(ii) in the case of a violation that continues after the Secretary provides written notice to

[2] See References in Text note below.

the responsible person, the responsible person shall be subject to a civil monetary penalty of $250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 355(*o*), 355(p), or 355–1 of this title for which the responsible person is subject to such civil penalty.

(5)(A) A civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order may be imposed, 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, or upon whom a no-tobacco-sale order is to be imposed, 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, or the period to be covered by a no-tobacco-sale order, 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. A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), (3), (4), or (9). 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.

(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty or the imposition of a no-tobacco-sale order and who is aggrieved by an order assessing a civil penalty or the imposition of a no-tobacco-sale order 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, or on which the no-tobacco-sale order was imposed, as the case may be.

(7) 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 (6), or

(B) after a court in an action brought under paragraph (6) 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 (6) 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.

(8) If the Secretary finds that a person has committed repeated violations of section 387f(d)(5) of this title or of restrictions promulgated under section 387f(d) of this title at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to 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, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

(A) IN GENERAL.—Subject to subparagraph (B), any person who violates a requirement of this chapter which relates to tobacco products 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.

(B) ENHANCED PENALTIES.—

(i) Any person who intentionally violates a requirement of section 387b(5), 387b(6), 387d, 387h(c), or 387k(a) of this title, shall be subject to a civil monetary penalty of—

(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000

for all such violations adjudicated in a single proceeding.

(ii) Any person who violates a requirement of section 387k(g)(2)(C)(ii) or 387k(i)(1) of this title, shall be subject to a civil monetary penalty of—

(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.

(g) Violations regarding direct-to-consumer advertising

(1) With respect to a person who is a holder of an approved application under section 355 of this title for a drug subject to section 353(b) of this title or under section 262 of title 42, any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this chapter (including the civil penalty in subsection (f)(4)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

(A) Whether the person submitted the advertisement or a similar advertisement for review under section 379h–1 of this title.

(B) Whether the person submitted the advertisement for review if required under section 353c[2] of this title.

(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

(G) Whether the violations were material.

(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.

(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this provision within the previous 1-year period.

(J) The scope and extent of any voluntary, subsequent remedial action by the person.

(K) Such other matters, as justice may require.

(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate such advertisement after incorporating each comment received from the Secretary.

(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

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

(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo 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 assessments was issued.

(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

(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 (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States 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 (6) 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; Pub. L. 108–173, title XI, § 1121(b)(2), Dec. 8, 2003, 117 Stat. 2469; Pub. L. 110–85, title II, § 226(b), title VIII, § 801(b)(2), title IX, §§ 901(d)(4), 902(b), Sept. 27, 2007, 121 Stat. 854, 920, 940, 943; Pub. L. 111–31, div. A, title I, § 103(c), June 22, 2009, 123 Stat. 1835; Pub. L. 111–353, title II, § 206(c), Jan. 4, 2011, 124 Stat. 3943; Pub. L. 112–144, title VII, § 716, July 9, 2012, 126 Stat. 1075; Pub. L. 113–54, title II, § 207(a), Nov. 27, 2013, 127 Stat. 640; Pub. L. 115–52, title VI, § 604(b), Aug. 18, 2017, 131 Stat. 1048; Pub. L. 116–94, div. N, title I, § 603(d)(2), Dec. 20, 2019, 133 Stat. 3124; Pub. L. 117–328, div. FF, title II, § 2513(b), Dec. 29, 2022, 136 Stat. 5805.)

Editorial Notes

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, 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.

Section 282(j)(5)(C)(ii) of title 42, referred to in subsec. (f)(3)(B), was in the original ''section 402(j)(5)(C)(ii)'', and was translated as meaning section 402(j)(5)(C)(ii) of the Public Health Service Act to reflect the probable intent of Congress because there is no subsec. (j) of section 402 of the Federal Food, Drug, and Cosmetic Act and section 402(j)(5)(C)(ii) of the Public Health Service Act relates to notification of noncompliance with clinical trial information requirements.

Section 353c of this title, referred to in subsec. (g)(3)(B), was in the original a reference to section 503B of act June 25, 1938, and was translated as if it referred to section 503C of that Act, to reflect the probable intent of Congress and the renumbering of section 503B as 503C by Pub. L. 113–54, title I, § 102(a)(1), Nov. 27, 2013, 127 Stat. 587, and its transfer to section 353c of this title. A new section 503B, which was enacted by section 102(a)(2) of Pub. L. 113–54, is classified to section 353b of this title and does not relate to television advertisements.

Amendments

2022—Subsec. (b)(8). Pub. L. 117–328, § 2513(b)(1), inserted '', or who violates section 331(fff)(3) of this title by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit device,'' after ''a counterfeit drug''.

Subsec. (c)(6). Pub. L. 117–328, § 2513(b)(2), added cl. (6).

2019—Subsec. (f)(8). Pub. L. 116–94 inserted ''section 387f(d)(5) of this title or of'' after ''repeated violations of''.

2017—Subsec. (b)(8). Pub. L. 115–52 added par. (8).

2013—Subsec. (b)(1)(D). Pub. L. 113–54 substituted ''353(e)(1)'' for ''353(e)(2)(A)''.

2012—Subsec. (b)(7). Pub. L. 112–144 added par. (7).

2011—Subsec. (f)(2)(A). Pub. L. 111–353 inserted ''or any person who does not comply with a recall order under section 350*l* of this title'' after ''section 342(a)(2)(B) of this title''.

2009—Subsec. (f)(5)(A). Pub. L. 111–31, § 103(c)(1)(A), (B), substituted ''paragraph (1), (2), (3), (4), or (9)'' for ''paragraph (1), (2), (3), or (4)'', ''shall be assessed, or a no-tobacco-sale order may be imposed,'' for ''shall be assessed'', and ''assessed a civil penalty, or upon whom a no-tobacco-sale order is to be imposed,'' for ''assessed a civil penalty''.

Subsec. (f)(5)(B). Pub. L. 111–31, § 103(c)(1)(C), inserted ''or the period to be covered by a no-tobacco-sale order,'' after ''penalty,'' and inserted at end ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''

Subsec. (f)(5)(C). Pub. L. 111–31, § 103(c)(1)(A), substituted ''paragraph (1), (2), (3), (4), or (9)'' for ''paragraph (1), (2), (3), or (4)''.

Subsec. (f)(5)(D). Pub. L. 111–31, § 103(c)(1)(D), added subpar. (D).

Subsec. (f)(6). Pub. L. 111–31, § 103(c)(2), inserted ''or the imposition of a no-tobacco-sale order'' after ''penalty'' in two places and substituted ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.'' for ''issued.''

Subsec. (f)(8), (9). Pub. L. 111–31, § 103(c)(3), added pars. (8) and (9).

2007—Subsec. (f). Pub. L. 110–85, § 226(b)(1), redesignated subsec. (g) as (f).

Subsec. (f)(1)(B)(ii). Pub. L. 110–85, § 226(b)(2), substituted ''360i(g)'' for ''360i(f)''.

Subsec. (f)(2)(C). Pub. L. 110–85, § 801(b)(2)(C), substituted ''paragraph (5)(A)'' for ''paragraph (3)(A)''.

Subsec. (f)(3). Pub. L. 110–85, § 801(b)(2)(B), added par. (3). Former par. (3) redesignated (5).

Subsec. (f)(4). Pub. L. 110–85, § 902(b)(1), added par. (4).

Pub. L. 110–85, § 801(b)(2)(A), redesignated par. (4) as (6).

Subsec. (f)(5). Pub. L. 110–85, §801(b)(2)(A), redesignated par. (3) as (5). Former par. (5) redesignated (7).

Subsec. (f)(5)(A), (C). Pub. L. 110–85, §902(b)(2), substituted ''paragraph (1), (2), (3), or (4)'' for ''paragraph (1), (2), or (3)''.

Pub. L. 110–85, §801(b)(2)(D), substituted ''paragraph (1), (2), or (3)'' for ''paragraph (1) or (2)''.

Subsec. (f)(6). Pub. L. 110–85, §801(b)(2)(A), (E), redesignated par. (4) as (6) and substituted ''paragraph (5)(A)'' for ''paragraph (3)(A)''.

Subsec. (f)(7). Pub. L. 110–85, §801(b)(2)(A), (F), redesignated par. (5) as (7) and substituted ''paragraph (6)'' for ''paragraph (4)'' wherever appearing.

Subsec. (g). Pub. L. 110–85, §901(d)(4), added subsec. (g).

Pub. L. 110–85, §226(b)(1), redesignated subsec. (g) as (f).

2003—Subsec. (b)(6). Pub. L. 108–173, which directed amendment of subsec. (a)(6) by substituting ''prescription drug under section 384(b)'' for ''covered product pursuant to section 384(a)'', was executed by making the substitution in subsec. (b)(6), to reflect the probable intent of Congress.

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).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2013 AMENDMENT

Pub. L. 113–54, title II, §207(b), Nov. 27, 2013, 127 Stat. 640, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect on January 1, 2015.''

EFFECTIVE DATE OF 2009 AMENDMENT

Pub. L. 111–31, div. A, title I, §103(q)(3), (4), June 22, 2009, 123 Stat. 1840, provided that:

''(3) GENERAL EFFECTIVE DATE.—The amendments made by paragraphs (2) [amending this section], (3) [amending this section], and (4) [no par. (4) has been enacted] of subsection (c) shall take effect upon the issuance of guidance described in paragraph (1) of this subsection [set out as a Guidance note below].

''(4) SPECIAL EFFECTIVE DATE.—The amendment made by subsection (c)(1) [amending this section] shall take effect on the date of enactment of this Act [June 22, 2009].''

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by sections 901(d)(4) and 902(b) of Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–322, title XXXIII, § 330015, Sept. 13, 1994, 108 Stat. 2146, 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

Pub. L. 101–629, § 17(b), Nov. 28, 1990, 104 Stat. 4528, 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

Act Oct. 26, 1951, ch. 578, § 3, 65 Stat. 649, 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.

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 provider [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].''

Executive Documents

TRANSFER OF FUNCTIONS

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

§ 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(*ll*), 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