

cord 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 provided [sic] such agent information to the Food and Drug Administration prior to the violation;

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

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

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

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

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

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

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

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

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

“(2) PENALTIES FOR VIOLATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111-353 to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

ENFORCEMENT

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

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 above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

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

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

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

(ii) is being held for sale to the ultimate consumer in an establishment other than an es-

tablishment owned or operated by a manufacturer, packer, or distributor of the food.

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

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

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

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

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

(b) Procedure; multiplicity of pending proceedings

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

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

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

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

(1) Any food, drug, device, tobacco product, or cosmetic condemned under this section shall,