

GUIDANCE

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

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

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

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

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

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

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

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

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

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

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

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

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

“(2) PENALTIES FOR VIOLATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONSTRUCTION OF 2011 AMENDMENT

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

ENFORCEMENT

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

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

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

§ 334. Seizure

(a) Grounds and jurisdiction

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