

**Food and Drug Administration, HHS**

**§ 17.2**

(e) Section 307 of the act authorizing civil money penalties for certain actions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.

(f) Section 539(b)(1) of the act authorizing civil money penalties for certain violations of the act that relate to electronic products.

(g) Section 351(d)(2) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(h) Section 354(h)(3) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998, authorizing civil money pen-

alties for failure to obtain a certificate and failure to comply with established standards, among other things.

(i) Section 2128(b)(1) of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers under section 2128 of the PHS Act.

(j) Section 303(f) of the act authorizing civil money penalties for any person who violates a requirement of the Family Smoking Prevention and Tobacco Control Act which relates to tobacco products.

[60 FR 38626, July 27, 1995, as amended at 69 FR 43301, July 20, 2004; 73 FR 66752, Nov. 12, 2008; 75 FR 73953, Nov. 30, 2010]

**§ 17.2 Maximum penalty amounts.**

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

**CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS**

U.S.C. Section	Former maximum penalty amount (in dollars)	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
<b>21 U.S.C.</b>				
333(b)(2)(A) .....	60,000 .....	For each of the first two violations in any 10-year period.	2013 .....	65,000.
333(b)(2)(B) .....	1,200,000 .....	For each violation after the second conviction in any 10-year period.	2013 .....	1,275,000.
333(b)(3) .....	120,000 .....	Per violation .....	2013 .....	130,000.
333(f)(1)(A) .....	16,500 .....	Per violation .....	2008 .....	16,500 (not adjusted).
333(f)(1)(A) .....	1,200,000 .....	For the aggregate of violations .....	2013 .....	1,275,000.
333(f)(2)(A) .....	55,000 .....	Per individual .....	2013 .....	60,000.
333(f)(2)(A) .....	300,000 .....	Per "any other person" .....	2013 .....	325,000.
333(f)(2)(A) .....	600,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	650,000.
333(f)(3)(A) .....	10,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	11,000.
333(f)(3)(B) .....	10,000 .....	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected.	2013 .....	11,000.
333(f)(4)(A)(i) .....	250,000 .....	Per violation .....	2013 .....	275,000.
333(f)(4)(A)(i) .....	1,000,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	1,075,000.
333(f)(4)(A)(ii) .....	250,000 .....	For the first 30-day period (or any portion thereof) of continued violation following notification.	2013 .....	275,000.
333(f)(4)(A)(ii) .....	1,000,000 .....	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation.	2013 .....	1,075,000.
333(f)(4)(A)(ii) .....	10,000,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	10,850,000.
333(f)(9)(A) .....	15,000 .....	Per violation .....	2009 .....	15,000 (not adjusted).

§ 17.2

21 CFR Ch. I (4–1–15 Edition)

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former maximum penalty amount (in dollars)	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
333(f)(9)(A) .....	1,000,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	1,050,000.
333(f)(9)(B)(i)(I) ..	250,000 .....	Per violation .....	2013 .....	275,000.
333(f)(9)(B)(i)(I) ..	1,000,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	1,050,000.
333(f)(9)(B)(i)(II)	250,000 .....	For the first 30-day period (or any portion thereof) of continued violation following notification.	2013 .....	275,000.
333(f)(9)(B)(i)(II)	1,000,000 .....	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation.	2013 .....	1,050,000.
333(f)(9)(B)(i)(II)	10,000,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	10,525,000.
333(f)(9)(B)(ii)(I)	250,000 .....	Per violation .....	2013 .....	275,000.
333(f)(9)(B)(ii)(I)	1,000,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	1,050,000.
333(f)(9)(B)(ii)(II)	250,000 .....	For the first 30-day period (or any portion thereof) of continued violation following notification.	2013 .....	275,000.
333(f)(9)(B)(ii)(II)	1,000,000 .....	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation.	2013 .....	1,050,000.
333(f)(9)(B)(ii)(II)	10,000,000 .....	For all violations adjudicated in a single proceeding.	2013 .....	10,525,000.
333(g)(1) .....	250,000 .....	For the first violation in any 3-year period.	2013 .....	275,000.
333(g)(1) .....	500,000 .....	For each subsequent violation in any 3-year period.	2013 .....	550,000.
333 note .....	250 .....	For the second violation (following a first violation with a warning) within a 12-month period by a retailer with an approved training program.	2009 .....	250 (not adjusted).
333 note .....	500 .....	For the third violation within a 24-month period by a retailer with an approved training program.	2009 .....	500 (not adjusted).
333 note .....	2,000 .....	For the fourth violation within a 24-month period by a retailer with an approved training program.	2009 .....	2,000 (not adjusted).
333 note .....	5,000 .....	For the fifth violation within a 36-month period by a retailer with an approved training program.	2009 .....	5,000 (not adjusted).
333 note .....	10,000 .....	For the sixth or subsequent violation within a 48-month period by a retailer with an approved training program.	2013 .....	11,000.
333 note .....	250 .....	For the first violation by a retailer without an approved training program.	2009 .....	250 (not adjusted).
333 note .....	500 .....	For the second violation within a 12-month period by a retailer without an approved training program.	2009 .....	500 (not adjusted).
333 note .....	1,000 .....	For the third violation within a 24-month period by a retailer without an approved training program.	2013 .....	1,100.
333 note .....	2,000 .....	For the fourth violation within a 24-month period by a retailer without an approved training program.	2009 .....	2,000 (not adjusted).
333 note .....	5,000 .....	For the fifth violation within a 36-month period by a retailer without an approved training program.	2009 .....	5,000 (not adjusted).
333 note .....	10,000 .....	For the sixth or subsequent violation within a 48-month period by a retailer without an approved training program.	2013 .....	11,000.

**Food and Drug Administration, HHS**

**§ 17.5**

**CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued**

U.S.C. Section	Former maximum penalty amount (in dollars)	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
335b(a) .....	300,000 .....	Per violation for an individual .....	2013 .....	325,000.
335b(a) .....	1,200,000 .....	Per violation for "any other person" .....	2013 .....	1,275,000.
360pp(b)(1) .....	1,100 .....	Per violation per person .....	2008 .....	1,100 (not adjusted).
360pp(b)(1) .....	355,000 .....	For any related series of violations	2013 .....	375,000.
<b>42 U.S.C.</b>				
263b(h)(3) .....	11,000 .....	Per violation .....	2008 .....	11,000 (not adjusted).
300aa-28(b)(1) ..	120,000 .....	Per occurrence .....	2013 .....	130,000.

[79 FR 6090, Feb. 3, 2014]

**§ 17.3 Definitions.**

The following definitions are applicable in this part:

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(g)(1):

(1) *Significant departure*, for the purpose of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.

(2) *Knowing departure*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from a requirement taken: (a) With actual knowledge that the action is such a departure, or (b) in deliberate ignorance of a requirement, or (c) in reckless disregard of a requirement.

(3) *Minor violations*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(ii), means departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential.

(4) *Defective*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a device, or any defect in mechanical, physical, or chemical properties of a device.

(b) *Person* or *respondent* includes an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, or other legal entity, or as may be defined in

the act or regulation pertinent to the civil penalty action being brought.

(c) *Presiding officer* means an administrative law judge qualified under 5 U.S.C. 3105.

(d) Any term that is defined in the act has the same definition for civil money penalty actions that may be brought under that act.

(e) Any term that is defined in Title 21 of the Code of Federal Regulations has the same definition for civil money penalty actions that may arise from the application of the regulation(s).

(f) Any term that is defined in the PHS Act has the same definition for civil money penalty actions that may be brought under that act.

(g) *Departmental Appeals Board (DAB)* means the Departmental Appeals Board of the Department of Health and Human Services.

**§ 17.5 Complaint.**

(a) The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint signed by the Office of the Chief Counsel attorney for the Center and by filing a copy of the complaint with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. For a civil money penalty action against retailers of tobacco products, the complaint may be signed by any Agency employee designated by the Chief Counsel.

(b) The complaint shall state: