

§ 17.2

21 CFR Ch. I (4–1–10 Edition)

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the 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)
21 U.S.C.				
333(b)(2)(A)	55,000	For each of the first two violations in any 10-year period	2008	60,000
333(b)(2)(B)	1,100,000	For each violation after the second conviction in any 10-year period	2008	1,200,000
333(b)(3)	110,000	Per violation	2008	120,000
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted)
333(f)(1)(A)	1,100,000	For the aggregate of violations	2008	1,200,000
333(f)(2)(A)	55,000	Per individual	2008	60,000
333(f)(2)(A)	275,000	Per "any other person"	2008	300,000
333(f)(2)(A)	550,000	For all violations adjudicated in a single proceeding	2008	600,000
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2007	10,000 (not adjusted)
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	2007	10,000 (not adjusted)
333(f)(4)(A)(i)	250,000	Per violation	2007	250,000 (not adjusted)
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2007	250,000 (not adjusted)
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 period	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2007	10,000,000 (not adjusted)
333(g)(1)	250,000	For the first violation in any 3-year period	2007	250,000 (not adjusted)
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2007	500,000 (not adjusted)
335b(a)	275,000	Per violation for an individual	2008	300,000
335b(a)	1,100,000	Per violation for "any other person"	2008	1,200,000

**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)
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted)
360pp(b)(1)	330,000	For any related series of violations	2008	355,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted)
300aa-28(b)(1)	110,000	Per occurrence	2008	120,000

[73 FR 66752, Nov. 12, 2008]

**§ 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 or-

ganizational 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.

(b) The complaint shall state: