

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) ¹	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
333 note	N/A	For the fifth violation within a 36-month period by a retailer without an approved training program	2009	5,000 (not adjusted).
333 note	N/A	For the six or subsequent violation within a 48-month period by a retailer without an approved training program	2009	10,000 (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.
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.

¹Maximum penalties assessed under The Family Smoking Prevention and Tobacco Control Act do not have a "former maximum penalty."

§ 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