

§ 17.1

21 CFR Ch. I (4–1–13 Edition)

§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that authorize civil money penalties that are governed by these procedures.

(a) Section 303(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

(b) Section 303(f)(1) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices and section 303(f)(2) of the act authorizing civil money penalties for certain violations of the act that relate to pesticide residues.

(c) Section 303(f)(3) of the act authorizing civil money penalties for certain violations relating to the submission of certifications and/or clinical trial information to the clinical trial data bank and section 303(f)(4) of the act authorizing civil money penalties for certain violations of the act relating to postmarket studies, clinical trial requirements, and risk evaluation and mitigation strategies for drugs.

(d) Section 303(g)(1) of the act authorizing civil money penalties for certain violations of the act that relate to dissemination of direct-to-consumer advertisements for approved drugs or biological products.

(e) Section 307 of the act authorizing civil money penalties for certain ac-

tions 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 penalties 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 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) ¹	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).