AUTHORITY: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

SOURCE: 60 FR 38626, July 27, 1995, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 17 appear at 68 FR 24879, May 9, 2003.

§ 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 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 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.

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