

## § 17.2

(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 manu-

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facturers 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 maximum civil money penalties associated with the statutory provisions authorizing civil money penalties under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act can be found at 45 CFR part 102. The table of these maximum civil money penalties can be found at 45 CFR 102.3.

[81 FR 62358, Sept. 9, 2016]

### § 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(f)(1):

(1) *Significant departure*, for the purpose of interpreting 21 U.S.C. 333(f)(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(f)(1)(B)(i), means a departure from a requirement taken:

(i) With actual knowledge that the action is such a departure; or

(ii) In deliberate ignorance of a requirement; or

(iii) In reckless disregard of a requirement.

(3) *Minor violations*, for the purposes of interpreting 21 U.S.C. 333(f)(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(f)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a

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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.

[60 FR 38626, July 27, 1995, as amended at 82 FR 34402, July 25, 2017]

### § 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 Dockets Management Staff (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:

(1) The allegations of liability against the respondent, including the statutory basis for liability, the identification of violations that are the basis for the alleged liability, and the reasons that the respondent is responsible for the violations;

(2) The amount of penalties and assessments that the Center is seeking;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the respondent's right to request a hearing by filing an answer and to retain counsel to represent the respondent; and

(4) That failure to file an answer within 30 days of service of the complaint will result in the imposition of the proposed amount of penalties and assessments, as provided in § 17.11.

(c) The Center may, on motion, subsequently amend its complaint to conform with the evidence adduced during the administrative process, as justice may require.

(d) The presiding officer will be assigned to the case upon the filing of the complaint under this part.

[60 FR 38626, July 27, 1995, as amended at 79 FR 6091, Feb. 3, 2014]

### § 17.7 Service of complaint.

(a) Service of a complaint may be made by:

(1) Certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt; or

(2) Delivery in person to:

(i) An individual respondent; or  
(ii) An officer or managing or general agent in the case of a corporation or unincorporated business.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:

(1) Affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery;

(2) A United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or

(3) Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent.

### § 17.9 Answer.

(a) The respondent may request a hearing by filing an answer with the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, within 30 days of service of the