

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:

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(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.

§ 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.

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§ 17.9 Answer.

(a) The respondent may request a hearing by filing an answer with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, within 30 days of service of the complaint. Unless stated otherwise, an answer shall be deemed to be a request for hearing.

(b) In the answer, the respondent:

(1) Shall admit or deny each of the allegations of liability made in the complaint; allegations not specifically denied in an answer are deemed admitted;

(2) Shall state all defenses on which the respondent intends to rely;

(3) Shall state all reasons why the respondent contends that the penalties and assessments should be less than the requested amount; and

(4) Shall state the name, address, and telephone number of the respondent's counsel, if any.

(c) If the respondent is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the respondent shall, before the expiration of 30 days from service of the complaint, file a request for an extension of time within which to file an answer that meets the requirements of paragraph (b) of this section. The presiding officer may, for good cause shown, grant the respondent up to 30 additional days within which to file an answer that meets the requirements of paragraph (b) of this section.

(d) The respondent may, on motion, amend its answer to conform with the evidence as justice may require.

§ 17.11 Default upon failure to file an answer.

(a) If the respondent does not file an answer within the time prescribed in §17.9 and if service has been effected as provided in §17.7, the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing: