

PART 17 CIVIL MONEY PENALTIES HEARINGS

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Sec. 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.

(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.

Sec. 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the Federal Food, Drug, and Cosmetic 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)	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
21 U.S.C.				
333(b) (2) (A)	60,000	For each of the first two violations in any 10-year period	2013	65,000.
333(b) (2) (B)	1,200,000	For each violation after the	2013	1,275,000.

		second conviction in any 10-year period		
333(b) (3)	120, 000	Per violation	2013	130, 000.
333(f) (1) (A)	16, 500	Per violation	2008	16, 500 (not adjusted).
333(f) (1) (A)	1, 200, 000	For the aggregate of violations	2013	1, 275, 000.
333(f) (2) (A)	55, 000	Per individual	2013	60, 000.
333(f) (2) (A)	300, 000	Per "any other person"	2013	325, 000.
333(f) (2) (A)	600, 000	For all violations adjudicated in a single proceeding	2013	650, 000.
333(f) (3) (A)	10, 000	For all violations adjudicated in a single proceeding	2013	11, 000.
333(f) (3) (B)	10, 000	For each day the violation is not corrected after a 30-day period following notification until the	2013	11, 000.

		violation is corrected		
333(f) (4) (A) (i)	250, 000	Per violation	2013	275, 000.
333(f) (4) (A) (i)	1, 000, 000	For all violations adjudicated in a single proceeding	2013	1, 075, 000.
333(f) (4) (A) (ii)	250, 000	For the first 30-day period (or any portion thereof) of continued violation following notification	2013	275, 000.
333(f) (4) (A) (ii)	1, 000, 000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation	2013	1, 075, 000.
333(f) (4) (A) (ii)	10, 000, 000	For all violations adjudicated in a single proceeding	2013	10, 850, 000.
333(f) (9) (A)	15, 000	Per violation	2009	15, 000 (not adjusted).
333(f) (9) (A)	1, 000, 000	For all	2013	1, 050, 000.

		violations adjudicated in a single proceeding		
333(f) (9) (B) (i) (I)	250, 000	Per violation	2013	275, 000.
333(f) (9) (B) (i) (I)	1, 000, 000	For all violations adjudicated in a single proceeding	2013	1, 050, 000.
333(f) (9) (B) (i) (II)	250, 000	For the first 30-day period (or any portion thereof) of continued violation following notification	2013	275, 000.
333(f) (9) (B) (i) (II)	1, 000, 000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation	2013	1, 050, 000.
333(f) (9) (B) (i) (II)	10, 000, 000	For all violations adjudicated in a single proceeding	2013	10, 525, 000.
333(f) (9) (B) (ii) (I)	250, 000	Per	2013	275, 000.

		violation		
333(f) (9) (B) (ii) (I)	1, 000, 000	For all violations adjudicated in a single proceeding	2013	1, 050, 000.
333(f) (9) (B) (ii) (II)	250, 000	For the first 30-day period (or any portion thereof) of continued violation following notification	2013	275, 000.
333(f) (9) (B) (ii) (II)	1, 000, 000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation	2013	1, 050, 000.
333(f) (9) (B) (ii) (II)	10, 000, 000	For all violations adjudicated in a single proceeding	2013	10, 525, 000.
333(g) (1)	250, 000	For the first violation in any 3-year period	2013	275, 000.
333(g) (1)	500, 000	For each subsequent	2013	550, 000.

		violation in any 3-year period		
333 note	250	For the second violation (following a first violation with a warning) within a 12-month period by a retailer with an approved training program	2009	250 (not adjusted).
333 note	500	For the third violation within a 24-month period by a retailer with an approved training program	2009	500 (not adjusted).

333 note	2,000	For the fourth violation within a 24-month period by a retailer with an approved training program	2009	2,000 (not adjusted).
333 note	5,000	For the fifth violation within a 36-month period by a retailer with an approved training program	2009	5,000 (not adjusted).
333 note	10,000	For the sixth or subsequent violation within a 48-month period by a retailer with an approved training program	2013	11,000.
333 note	250	For the first violation by a retailer without an approved training	2009	250 (not adjusted).

		program		
333 note	500	For the second violation within a 12-month period by a retailer without an approved training program	2009	500 (not adjusted).
333 note	1,000	For the third violation within a 24-month period by a retailer without an approved training program	2013	1,100.
333 note	2,000	For the fourth violation within a 24-month period by a retailer without an approved training program	2009	2,000 (not adjusted).
333 note	5,000	For the fifth violation within a 36-month period by a retailer	2009	5,000 (not adjusted).

		without an approved training program		
333 note	10,000	For the sixth or subsequent violation within a 48-month period by a retailer without an approved training program	2013	11,000.
335b (a)	300,000	Per violation for an individual	2013	325,000.
335b (a)	1,200,000	Per violation for "any other person"	2013	1,275,000.
360pp (b) (1)	1,100	Per violation per person	2008	1,100 (not adjusted).
360pp (b) (1)	355,000	For any related series of violations	2013	375,000.
42 U. S. C.				
263b (h) (3)	11,000	Per violation	2008	11,000 (not adjusted).
300aa-28 (b) (1)	120,000	Per occurrence	2013	130,000.

Sec. 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.

Sec. 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. 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.

Sec. 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.

Sec. 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.

Sec. 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:

(1) The maximum amount of penalties provided for by law for the violations alleged; or

(2) The amount asked for in the complaint, whichever amount is smaller.

(b) Except as otherwise provided in this section, by failing to file a timely answer, the respondent waives any right to a hearing and to contest the amount of the penalties and assessments imposed under paragraph (a) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(c) If, before such a decision becomes final, the respondent files a motion seeking to reopen on the grounds that extraordinary circumstances prevented the respondent from filing an answer, the initial decision shall be stayed pending a decision on the motion.

(d) If, on such motion, the respondent can demonstrate extraordinary circumstances excusing the failure to file an answer in a timely manner, the presiding officer may withdraw the decision under paragraph (a) of this section, if such a decision has been issued, and shall grant the respondent an opportunity to answer the complaint as provided in 17.9(a).

(e) If the presiding officer decides that the respondent's failure to file an answer in a timely manner is not excused, he or she shall affirm the decision under paragraph (a) of this section, and the decision shall become final and binding upon the parties 30 days after the presiding officer issues the decision on the respondent's motion filed under paragraph (c) of this section.

Sec. 17.13 Notice of hearing.

After an answer has been filed, the Center shall serve a notice of hearing on the respondent. Such notice shall include:

(a) The date, time, and place of a prehearing conference, if any, or the date, time, and place of the hearing if there is not to be a prehearing conference;

(b) The nature of the hearing and the legal authority and jurisdiction under which the hearing is to be held;

(c) A description of the procedures for the conduct of the hearing;

(d) The names, addresses, and telephone numbers of the representatives of the government and of the respondent, if any; and

(e) Such other matters as the Center or the presiding officer deems appropriate.

Sec. 17.15 Parties to the hearing.

(a) The parties to the hearing shall be the respondent and the Center(s) with jurisdiction over the matter at issue. No other person may participate.

(b) The parties may at any time prior to a final decision by the entity deciding any appeal agree to a settlement of all or a part of the matter. The settlement agreement shall be filed in the docket and shall constitute complete or partial resolution of the administrative case as so designated by the settlement agreement. The settlement document shall be effective upon filing in the docket and need not be ratified by the presiding officer or the Commissioner of Food and Drugs.

(c) The parties may be represented by counsel, who may be present at the hearing.

Sec. 17.17 Summary decisions.

(a) At any time after the filing of a complaint, a party may move, with or without supporting affidavits (which, for purposes of this part, shall include declarations under penalty of perjury), for a summary decision on any issue in the hearing. The other party may, within 30 days after service of the motion, which may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision.

The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law.

(c) Affidavits shall set forth only such facts as would be admissible

in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated. When a motion for summary decision is made and supported as provided in this regulation, a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing.

(d) If, on motion under this section, a summary decision is not rendered on all issues or for all the relief asked, and if additional facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings on facts still at issue. The facts specified not to be at issue shall be deemed established.

(e) Except as provided in 17.18, a party may not obtain interlocutory review by the entity deciding the appeal (currently the DAB) of a partial summary decision of the presiding officer. A review of final summary decisions on all issues may be had through the procedure set forth in 17.47.

Sec. 17.18 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section, rulings of the presiding officer may not be appealed before consideration on appeal of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the entity deciding the appeal (currently the DAB) if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made, a participant may file a brief on the appeal only if specifically authorized by the presiding officer or the entity deciding the appeal (currently the DAB), and if such authorization is granted, only within the period allowed by the presiding officer or the entity deciding the appeal. If a participant

is authorized to file a brief, any other participant may file a brief in opposition, within the period allowed by the entity deciding the appeal (currently the DAB). The deadline for filing an interlocutory appeal is subject to the discretion of the presiding officer.

Sec. 17.19 Authority of the presiding officer.

(a) The presiding officer shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The presiding officer has the authority to:

(1) Set and change the date, time, and place of the hearing on reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable time;

(3) Require parties to attend conferences for settlement, to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery consistent with 17.23;

(8) Regulate the course of the hearing and the conduct of the parties;

(9) Examine witnesses;

(10) Upon motion of a party for good cause shown, the presiding officer may allow a witness to be recalled for additional testimony;

(11) Receive, rule on, exclude, or limit evidence;

(12) Upon motion of a party or on the presiding officer's own motion, take official notice of facts;

(13) Upon motion of a party, decide cases, in whole or in part, by summary decision when there is no genuine issue of material fact;

(14) Conduct any conference, argument, or hearing on motions in person or by telephone;

(15) Consolidate related or similar proceedings or sever unrelated matters;

- (16) Limit the length of pleadings;
 - (17) Waive, suspend, or modify any rule in this part if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;
 - (18) Issue protective orders pursuant to 17.28; and
 - (19) Exercise such other authority as is necessary to carry out the responsibilities of the presiding officer under this part.
- (c) The presiding officer does not have the authority to find Federal statutes or regulations invalid.

Sec. 17.20 Ex parte contacts.

No party or person (except employees of the presiding officer's office) shall communicate in any way with the presiding officer on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

Sec. 17.21 Prehearing conferences.

- (a) The presiding officer may schedule prehearing conferences as appropriate.
- (b) Upon the motion of any party, the presiding officer shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.
- (c) The presiding officer may use a prehearing conference to discuss the following:
 - (1) Simplification of the issues;

- (2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;
 - (3) Stipulations and admissions of fact as to the contents and authenticity of documents;
 - (4) Whether the parties can agree to submission of the case on a stipulated record;
 - (5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;
 - (6) Limitation of the number of witnesses;
 - (7) Scheduling dates for the exchange of witness lists and of proposed exhibits;
 - (8) Discovery and scheduling dates for completion of discovery;
 - (9) The date, time, and place for the hearing; and
 - (10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.
- (d) The presiding officer shall issue an order containing all matters agreed upon by the parties or ordered by the presiding officer at a prehearing conference.

Sec. 17.23 Discovery.

- (a) No later than 60 days prior to the hearing, unless otherwise ordered by the presiding officer, a party may make a request to another party for production, inspection, and copying of documents that are relevant to the issues before the presiding officer. Documents must be provided no later than 30 days after the request has been made.
- (b) For the purpose of this part, the term *documents* includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form readily accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions, and any forms of discovery, other than those permitted under paragraphs (a) and (e) of this section, are not authorized.

(d) (1) Within 10 days of service of a request for production of documents, a party may file a motion for a protective order.

(2) The presiding officer may grant a motion for a protective order, in whole or in part, if he or she finds that the discovery sought:

(i) Is unduly costly or burdensome,

(ii) Will unduly delay the proceeding, or

(iii) Seeks privileged information.

(3) The burden of showing that a protective order is necessary shall be on the party seeking the order.

(4) The burden of showing that documents should be produced is on the party seeking their production.

(e) The presiding officer shall order depositions upon oral questions only upon a showing that:

Sec. 17.25 Exchange of witness lists, witness statements, and exhibits.

(1) The information sought cannot be obtained by alternative methods, and

(2) There is a substantial reason to believe that relevant and probative evidence may otherwise not be preserved for presentation by a witness at the hearing.

(a) At least 30 days before the hearing, or by such other time as is specified by the presiding officer, the parties shall exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including written testimony.

(b) (1) If a party objects to the proposed admission of evidence not

exchanged in accordance with paragraph (a) of this section, the presiding officer will exclude such evidence if he or she determines that the failure to comply with paragraph (a) of this section should result in its exclusion.

(2) Unless the presiding officer finds that extraordinary circumstances justified the failure to make a timely exchange of witness lists under paragraph (a) of this section, he or she must exclude from the party's hearing evidence the testimony of any witness whose name does not appear on the witness list.

(3) If the presiding officer finds that extraordinary circumstances existed, the presiding officer must then determine whether the admission of the testimony of any witness whose name does not appear on the witness lists exchanged under paragraph (a) of this section would cause substantial prejudice to the objecting party. If the presiding officer finds that there is not substantial prejudice, the evidence may be admitted. If the presiding officer finds that there is substantial prejudice, the presiding officer may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless a party objects within 5 days prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

Sec. 17.27 Hearing subpoenas.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may, when authorized by law, request that the presiding officer issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 20 days before the date fixed for the hearing unless otherwise allowed by the presiding officer, upon a showing by the party of good cause. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location

thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed for service of a complaint in 17.7.

(f) If a party or the individual to whom the subpoena is directed believes a subpoena to be unreasonable, oppressive, excessive in scope, or unduly burdensome, or if it wishes to raise any other objection or privilege recognized by law, the party or individual may file a motion to quash the subpoena within 10 days after service or on or before the time specified in the subpoena for compliance if it is less than 10 days after service. Such a filing will state the basis for the motion to quash. The presiding officer may quash or modify the subpoena or order it implemented, as justice may require.

Sec. 17.28 Protective order.

(a) A party or a prospective witness may file a motion for a protective order with respect to discovery sought by a party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) When issuing a protective order, the presiding officer may make any order which justice requires to protect a party or person from oppression or undue burden or expense, or to protect trade secrets or confidential commercial information, as defined in 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under 21 CFR part 20. Such orders may include, but are not limited to, one or more of the following:

- (1) That the discovery not be had;
- (2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;
- (3) That the discovery may be had only through a method of discovery

provided for by this part other than that requested;

(4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;

(5) That the contents of discovery or evidence be sealed;

(6) That the information not be disclosed to the public or be disclosed only in a designated way; or

(7) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the presiding officer.

Sec. 17.29 Fees.

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in a United States District Court. A check for witness fees and mileage shall accompany the subpoena when served.

Sec. 17.30 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act or event, and includes the last day of the period, unless either such day is a Saturday, Sunday, or Federal holiday, in which event the time includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and Federal holidays shall be excluded from the computation.

(c) When a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response.

Sec. 17.31 Form, filing, and service of papers.

(a) *Form.* (1) Documents filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, shall include an original and two copies.

(2) The first page of every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the Office of the Chief Counsel, and designation of the pleading or paper (e.g., "motion to quash subpoena").

(3) Every pleading shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the pleading was filed, or his or her counsel.

(4) Pleadings or papers are considered filed when they are received by the Division of Dockets Management.

(b) *Service.* A party filing a document with the Division of Dockets Management under this part shall, no later than the time of filing, serve a copy of such document on every other party. Service upon any party of any document, other than service of a complaint, shall be made by delivering a copy personally or by placing a copy of the document in the United States mail or express delivery service, postage prepaid and addressed, to the party's last known address. When a party is represented by counsel, service shall be made on such counsel in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the time and manner of service, shall be proof of service.

Sec. 17.32 Motions.

(a) Any application to the presiding officer for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, delivered to the presiding officer, and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The presiding officer may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the presiding officer, any party may file a response to such motion.

(d) The presiding officer may not grant a written motion before the time for filing responses thereto has expired, except upon consent of

the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

Sec. 17.33 The hearing and burden of proof.

(a) The presiding officer shall conduct a hearing on the record to determine whether the respondent is liable for a civil money penalty and, if so, the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors.

(b) In order to prevail, the Center must prove respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

(c) The respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the presiding officer, who may order closure only to protect trade secrets or confidential commercial information, as defined in 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20 of this chapter.

Sec. 17.34 Determining the amount of penalties and assessments.

(a) When determining an appropriate amount of civil money penalties and assessments, the presiding officer and the Commissioner of Food and Drugs or entity designated by the Commissioner to decide the appeal (currently the DAB) shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.

(b) The presiding officer and the entity deciding the appeal shall refer to the factors identified in the statute under which the penalty is assessed for purposes of determining the amount of penalty.

(c) Nothing in this section shall be construed to limit the presiding officer or the entity deciding the appeal from considering any other

Sec. 17.35 Sanctions.

factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

(a) The presiding officer may sanction a person, including any party or counsel for:

(1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with a discovery order, including discovery and subpoena provisions of this part, the presiding officer may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(3) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) The presiding officer may exclude from participation in the hearing any legal counsel, party, or witness who refuses to obey an order of the presiding officer. In the case of repeated refusal, the presiding officer may grant judgment to the opposing party.

(e) If a party fails to prosecute or defend an action under this part after service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

(f) The presiding officer may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion or in compliance with the rules of this part.

(g) Sanctions imposed under this section may be the subject of an interlocutory appeal as allowed in 17.18(b), provided that no such appeal will stay or delay a proceeding.

Sec. 17.37 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) Direct testimony shall be admitted in the form of a written declaration submitted under penalty of perjury. Any such written declaration must be provided to all other parties along with the last known address of the witness. Any prior written statements of witnesses proposed to testify at the hearing shall be exchanged as provided in 17.25(a).

(c) The presiding officer shall exercise reasonable control over the manner and order of questioning witnesses and presenting evidence so as to:

(1) Make the examination and presentation effective for the ascertainment of the truth;

(2) Avoid undue consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The presiding officer shall permit the parties to conduct such cross-examination as may be required for a full disclosure of the facts.

(e) At the discretion of the presiding officer, a witness may be cross-examined on relevant matters without regard to the scope of his or her direct examination. To the extent permitted by the presiding

officer, a witness may be cross-examined on relevant matters with regard to the scope of his or her direct examination. To the extent permitted by the presiding officer, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the presiding officer may order witnesses excluded so that they cannot hear the testimony of the other witnesses. This rule does not authorize exclusion of:

- (1) A party who is an individual;
- (2) In the case of a party that is not an individual, an officer or employee of the party designated to be the party's sole representative for purposes of the hearing; or
- (3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by a party engaged in assisting counsel for the party.

(g) If a witness' testimony is submitted in writing prior to cross-examination, the cross-examining party need not subpoena the witness or pay for his or her travel to the hearing. The sponsoring party is responsible for producing the witness at its own expense, and failure to do so shall result in the striking of the witness' testimony.

Sec. 17.39 Evidence.

(a) The presiding officer shall determine the admissibility of evidence.

(b) Except as provided in this part, the presiding officer shall not be bound by the "Federal Rules of Evidence." However, the presiding officer may apply the "Federal Rules of Evidence" when appropriate, e.g., to exclude unreliable evidence.

(c) The presiding officer shall exclude evidence that is not relevant or material.

(d) Relevant evidence may be excluded if its probative value is

substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Relevant evidence may be excluded if it is privileged under Federal law.

(f) Evidence of furnishing or offering or promising to furnish, or accepting or offering or promising to accept, a valuable consideration in settling or attempting to settle a civil money penalty assessment which was disputed as to either validity or amount, is not admissible to prove liability for or invalidity of the civil money penalty or its amount. Evidence of conduct or statements made in settlement negotiations is likewise not admissible. This rule does not require the exclusion of any evidence otherwise discoverable merely because it is presented in the course of settlement negotiations. This rule also does not require exclusion when the evidence is offered for another purpose, such as proving bias or prejudice of a witness or opposing a contention of undue delay.

(g) The presiding officer may in his or her discretion permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the presiding officer pursuant to 17.28.

Sec. 17.41 The administrative record.

(a) The hearing will be recorded and transcribed. Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections. Transcripts may be obtained following the hearing from the Division of Dockets Management at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits, and other evidence admitted at the hearing and all papers and requests filed in the proceeding

constitute the administrative record for the decision by the presiding officer and the entity designated by the Commissioner of Food and Drugs to decide the appeal, currently the DAB.

(c) The administrative record may be inspected and copied (upon payment of a reasonable fee) by anyone unless otherwise ordered by the presiding officer, who shall upon motion of any party order otherwise when necessary to protect trade secrets or confidential commercial information, as defined in 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20.

Sec. 17.43 Posthearing briefs.

Any party may file a posthearing brief. The presiding officer shall fix the time for filing such briefs (which shall be filed simultaneously), which shall not exceed 60 days from the date the parties received the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The presiding officer may permit the parties to file responsive briefs. No brief may exceed 30 pages (exclusive of proposed findings and conclusions) unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer briefs, in which case the presiding officer may set a longer page limit. Proposed findings of fact and conclusions of law shall not exceed 30 pages unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer proposed findings and conclusions, in which case the presiding officer may set a longer page limit.

Sec. 17.45 Initial decision.

(a) The presiding officer shall issue an initial decision based only on the administrative record. The decision shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

- (1) Whether the allegations in the complaint are true, and, if so, whether respondent's actions identified in the complaint violated the law;
- (2) Whether any affirmative defenses are meritorious; and
- (3) If the respondent is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering

any mitigating or aggravating factors that he or she finds in the case.

(c) The presiding officer shall serve the initial decision or the decision granting summary decision on all parties within 90 days after the time for submission of posthearing briefs and responsive briefs (if permitted) has expired. If the presiding officer believes that he or she cannot meet the 90-day deadline, he or she shall notify the Commissioner of Food and Drugs or other entity designated by the Commissioner to decide the appeal of the reason(s) therefor, and the Commissioner or that entity may then set a new deadline.

(d) Unless the initial decision or the decision granting summary decision of the presiding officer is timely appealed, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after it is issued by the presiding officer.

Sec. 17.47 Appeals.

(a) Either the Center or any respondent may appeal an initial decision, including a decision not to withdraw a default judgment, or a decision granting summary decision to the Commissioner of Food and Drugs or other entity the Commissioner designates to decide the appeal. The Commissioner has currently designated the Departmental Appeals Board (DAB) to decide appeals under this part. Parties may appeal to the DAB by filing a notice of appeal with the DAB, Appellate Division MS6127, Departmental Appeals Board, United States Department of Health and Human Services, 330 Independence Ave. SW., Cohen Bldg., rm. G-644, Washington, DC 20201, and the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, in accordance with this section.

(b) (1) A notice of appeal may be filed at any time within 30 days after the presiding officer issues an initial decision or decision granting summary decision.

(2) The Commissioner or the entity designated by the Commissioner to hear appeals may, within his or her discretion, extend the initial 30-day period for an additional period of time if the Center or any respondent

files a request for an extension within the initial 30-day period and shows good cause.

(c) A notice of appeal shall be accompanied by a written brief of no greater length than that allowed for the posthearing brief. The notice must identify specific exceptions to the initial decision, must support each exception with citations to the record, and must explain the basis for each exception.

(d) The opposing party may file a brief of no greater length than that allowed for the posthearing brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief, unless such time period is extended by the Commissioner or the entity designated by the Commissioner to hear appeals on request of the opposing party for good cause shown. Any brief in opposition to exceptions shall be filed with the Division of Dockets Management and the DAB (addresses above).

(e) The appellant may file a reply brief not more than 10 pages in length within 10 days of being served with appellee's brief.

(f) There is no right to appear personally before the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB).

(g) The entity deciding the appeal will consider only those issues raised before the presiding officer, except that the appellee may make any argument based on the record in support of the initial decision or decision granting summary decision.

(h) If on appeal the entity deciding the appeal considers issues not adequately briefed by the parties, the entity may ask for additional briefing. However, no such additional briefs will be considered unless so requested.

(i) If any party demonstrates to the satisfaction of the entity deciding the appeal (currently the DAB) that additional evidence not presented at the hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the entity deciding the appeal may remand the matter to the presiding officer for consideration of the additional evidence.

(j) The Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) will issue a decision on the appeal within 60 days, if practicable, of the due date for submission of the appellee's brief. In the decision, the entity deciding the appeal may decline to review the case, affirm the initial decision or decision granting

summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by the presiding officer in the initial decision. If the entity deciding the appeal declines to review the case, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after the declination by the entity deciding the appeal.

(k) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

Sec. 17.48 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the presiding officer or by any of the parties is grounds for vacating, modifying, or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the presiding officer or the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) to be inconsistent with substantial justice. The presiding officer and the entity deciding the appeal at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

Sec. 17.51 Judicial review.

(a) The final decision of the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) constitutes final agency action from which a respondent may petition for judicial review under

the statutes governing the matter involved. Although the filing of a petition for judicial review does not stay a decision under this part, a respondent may file a petition for stay of such decision under 10.35 of this chapter.

(b) The Chief Counsel of FDA has been designated by the Secretary of Health and Human Services as the officer on whom copies of petitions for judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the entity deciding the appeal (currently the DAB).

(c) Exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review.

Sec. 17.54 Deposit in the Treasury of the United States.

All amounts assessed pursuant to this part shall be delivered to the Director, Division of Financial Management (HFA-100), Food and Drug Administration, rm. 11-61, 5600 Fishers Lane, Rockville, MD 20857, and shall be deposited as miscellaneous receipts in the Treasury of the United States.



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