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(c) Persons may use their alloted time in whatever way they wish, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 15.25. The presiding officer may allot additional time to any person when the officer concludes that it is in the public interest, but may not reduce the time allotted for any person without the consent of the person.

(d) If a person is not present at the time specified for the presentation, the persons following will appear in order, with adjustments for those appearing at their scheduled time. An attempt will be made to hear any person who is late at the conclusion of the hearing. Other interested persons attending the hearing who did not request an opportunity to make an oral presentation will be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

(a) The administrative record of a public hearing before the Commissioner consists of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions under § 15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding will be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Sec.
16.1 Scope.
16.5 Inapplicability and limited applicability.

Subpart B—Initiation of Proceedings

16.22 Initiation of regulatory hearing.
16.24 Regulatory hearing required by the act or a regulation.
16.26 Denial of hearing and summary decision.

Subpart C—Commissioner and Presiding Officer

16.40 Commissioner.
16.42 Presiding officer.
16.44 Communication to presiding officer and Commissioner.

Subpart D—Procedures for Regulatory Hearing

16.60 Hearing procedure.
16.62 Right to counsel.

Subpart E—Administrative Record and Decision

16.80 Administrative record of a regulatory hearing.
16.85 Examination of administrative record.
16.95 Administrative decision and record for decision.

Subpart F—Reconsideration and Stay

16.119 Reconsideration and stay of action.

Subpart G—Judicial Review

16.120 Judicial review.

AUTHORITY: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

SOURCE: 44 FR 22367, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no procedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices (see § 800.55(g) of this chapter).

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(e)(3) of the act relating to the temporary suspension of approval of a premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516 of the act relating to a proposed banned device regulations (see § 895.21(d) of this chapter).

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 518(e) of the act relating to a cease distribution and notification order or mandatory recall order concerning a medical device for human use.

Section 520(f)(2)(D) of the act relating to exemptions or variances from device current good manufacturing practice requirements (see § 820.1(d)).

Section 520(g)(4) and (g)(5) of the act relating to disapproval and withdrawal of approval of an application from an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c) of this chapter).

(2) Regulatory provisions:

§ 56.121(a), relating to disqualifying an institutional review board or an institution.

§ 71.37(a), relating to use of food containing a color additive.

§ 80.31(b), relating to refusal to certify a batch of a color additive.

§ 80.34(b), relating to suspension of certification service for a color additive.

§ 99.401(c), relating to a due diligence determination concerning the conduct of studies necessary for a supplemental application for a new use of a drug or device.

§ 130.17(1), relating to a temporary permit to vary from a food standard.

§ 170.17(b), relating to use of food containing an investigational food additive.

§ 202.1(j)(5), relating to approval of prescription drug advertisements.

§ 312.70, relating to whether an investigator is entitled to receive investigational new drugs.

§ 312.70(d) and 312.44, relating to termination of an IND for a sponsor.

§ 312.160(b), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

§ 511.1(b)(5), relating to use of food containing an investigational new animal drug.

§ 511.1(c)(1), relating to termination of an INAD for an investigator.

§ 511.1(c) (4) and (d), relating to termination of an INAD for a sponsor.

§ 814.46(c) relating to withdrawal of approval of a device premarket approval application.

§ 900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.

§ 900.14, relating to suspension or revocation of a mammography certificate.
§ 900.25, relating to approval or withdrawal of approval of certification agencies.
§ 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.
§ 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.
§ 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.
§ 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.
§ 1270.15(e), relating to the retention, recall, and destruction of human tissue.

[44 FR 22367, Apr. 13, 1979, as amended at 45 FR 3750, Jan 18, 1980; 45 FR 10332, Feb. 15, 1980; 46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 51 FR 26364, July 22, 1986; 54 FR 9037, Mar. 3, 1989; 57 FR 58403, Dec. 10, 1992; 58 FR 65520, Dec. 14, 1993; 62 FR 40444, July 29, 1997; 62 FR 55976, Oct. 28, 1997; 63 FR 26697, May 13, 1998; 63 FR 64581, Nov. 20, 1998; 67 FR 5467, Feb. 6, 2002]

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act and § 1.94, or of an electronic product under section 360(a) of the Public Health Service Act and § 1005.20.

(3) Factory inspections, recalls (except mandatory recalls of medical devices intended for human use), regulatory letters, and similar compliance activities related to law enforcement.

(4) A hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and §§ 101.17(h) and 115.50 of this chapter.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in subpart A of part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

[44 FR 22367, Apr. 13, 1979, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 76110, Dec. 5, 2000]

Subpart B—Initiation of Proceedings

§ 16.22 Initiation of regulatory hearing.

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the FDA employee to whom any request for hearing is to be addressed.

(5) Refer to FDA's guideline on electronic media coverage of its administrative proceedings (21 CFR part 10, subpart C).

(b) A person offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 3 working days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated FDA employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Commissioner will designate a presiding officer, and the hearing will take place at a time and location agreed upon by the party requesting the hearing, the FDA,

and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section will not operate to delay or stay any administrative action, including enforcement action by the agency unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

[44 FR 22367, Apr. 13, 1979, as amended at 49 FR 32173, Aug. 13, 1984]

§ 16.24 Regulatory hearing required by the act or a regulation.

(a) A regulatory hearing required by the act or a regulation under § 16.1(b) will be initiated in the same manner as other regulatory hearings subject to the additional procedures in this section.

(b) [Reserved]

(c) The notice will state whether any action concerning the matter that is the subject of the opportunity for hearing is or is not being taken pending the hearing under paragraph (d) of this section.

(d) The Commissioner may take such action pending a hearing under this section as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis.

(e) The hearing may not be required to be held at a time less than 2 working days after receipt of the request for hearing.

(f) Before the hearing, FDA will give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by FDA at the hearing in support of the decision or action. This information may be given orally or in writing, in the discretion of FDA.

(g) FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy will also be provided in advance if the other participant could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission concerning the article or information.

[44 FR 22367, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982; 54 FR 9037, Mar. 3, 1989]

§ 16.26 Denial of hearing and summary decision.

(a) A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom the authority to make the final decision on the matter has been delegated under part 5 determines that no genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(b) After a hearing commences, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. For the purpose of this paragraph, a hearing commences upon the receipt by FDA of a request for hearing submitted under § 16.22(b).

(c) The Commissioner or his or her delegate may review any summary decision of the presiding officer issued under paragraph (b) of this section at the request of a party or on the Commissioner's or his or her delegate's own initiative.

[53 FR 4615, Feb. 17, 1988]

Subpart C—Commissioner and Presiding Officer

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority under part 5 on a matter for which a regulatory hearing is available under this part, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a center director.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, or, consistent with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a center director, the presiding officer may be an official in another center or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted, as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989; 67 FR 53306, Aug. 15, 2002]

§ 16.44 Communication to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding officer or the Commissioner, e.g., a response by the presiding officer to a request for a change in the time of the hearing, is to be sent to all participants by the person writing the letter or the memorandum.

Subpart D—Procedures for Regulatory Hearing

§ 16.60 Hearing procedure.

(a) A regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a

trade secret or confidential commercial or financial information that is not available for public disclosure under § 20.61; or to protect investigatory records complied for law enforcement purposes that are not available for public disclosure under § 20.64.

(1) The Commissioner may determine that a regulatory hearing is closed either on the Commissioner's initiative or on a request by the party asking for a regulatory hearing, in the request for the hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 20.81(a) and FDA representatives with a direct professional interest in the subject matter of the proceeding are entitled to attend.

(b) A regulatory hearing will be conducted by a presiding officer. Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing may then present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of this part.

[44 FR 22367, Apr. 13, 1979, as amended at 66 FR 6469, Jan. 22, 2001; 66 FR 12850, Mar. 1, 2001]

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and comments on the report under § 16.60(e).

(5) All letters and memoranda of meetings or communications between

participants and the presiding officer or the Commissioner referred to in §16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under §16.1(a), the Commissioner shall consider the administrative record of the hearing specified in §16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under §16.1(b)—

(1) The administrative record of the hearing specified in §16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under §10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under §10.33 or may petition for a stay of the decision or action under §10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

Subpart G—Judicial Review

§16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part

PART 17—CIVIL MONEY PENALTIES HEARINGS

Sec.
17.1 Scope.
17.3 Definitions.
17.5 Complaint.
17.7 Service of complaint.
17.9 Answer.
17.11 Default upon failure to file an answer.
17.13 Notice of hearing.
17.15 Parties to the hearing.
17.17 Summary decisions.
17.18 Interlocutory appeal from ruling of presiding officer.
17.19 Authority of the presiding officer.
17.20 Ex parte contacts.
17.21 Prehearing conferences.
17.23 Discovery.
17.25 Exchange of witness lists, witness statements, and exhibits.
17.27 Hearing subpoenas.
17.28 Protective order.
17.29 Fees.
17.30 Computation of time.
17.31 Form, filing, and service of papers.
17.32 Motions.
17.33 The hearing and burden of proof.
17.34 Determining the amount of penalties and assessments.
17.35 Sanctions.
17.37 Witnesses.
17.39 Evidence.
17.41 The administrative record.
17.43 Posthearing briefs.
17.45 Initial decision.
17.47 Appeals.
17.48 Harmless error.
17.51 Judicial review.
17.54 Deposit in the Treasury of the United States.

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.