
GENERAL REVIEW AND ENFORCEMENT POLICIES

MANAGEMENT OF FORMAL EVIDENTIARY HEARINGS

When the Center Director refuses to approve an application or proposes to withdraw approval of an application, he/she must send to the applicant and publish in the Federal Register a Notice of Opportunity for a Hearing (NOOH) specifying the grounds upon which he/she will issue this order. The applicant has 30 days to respond after publication of the NOOH in the Federal Register.

This document describes the responsibilities of CVM personnel selected to assist Office of Chief Counsel, in its function as Agency lawyer, to identify and litigate the issues giving rise to the Administrative hearing.

1. Purpose:

These procedures have been developed as general guidelines for the management of formal evidentiary hearing procedures in which the Center may become involved. Deviation from these procedures may be necessary in individual cases.

2. Authority:

The statute and regulations governing the hearing process are extensive and involved. However, some of the sections pertaining to the process are as follows:

a. Federal Food, Drug, and Cosmetic Act

- (1) 512(c)(1) - Applies to New Animal Drug Applications
 - (a) 512(c)(1)(A) - Approval of Applications
 - (b) 512(c)(1)(B) - Notice of opportunity for a hearing on whether an application is approvable. (Expedited basis)
 - (c) 512(c)(2) - Applies to Abbreviated New Animal Drug Applications
- (2) 512(d) - Criteria for an order refusing approval of an application.
- (3) 512(e) - Criteria for an order withdrawing approval after due notice and opportunity for a hearing.
- (4) 512(m) - Application for the manufacture of an animal feed containing a new animal drug. An opportunity for a hearing given in accordance with 512(m)(2)(A); 512(m)(2)(B); 512(m)(3); or 512(m)(4).

- (5) 701(c) - Granting of formal evidentiary hearings.
- b. Title 21 of the Code of Federal Regulations
 - (1) 514.200 - Contents of Notice of Opportunity for a Hearing.
 - (2) 514.201 - Procedure for hearings
 - (3) Part 10 - Regulations Governing the Administrative Practices and Procedures of FDA.
 - (4) Part 12 - Formal Evidentiary Public Hearing.
 - (a) Subpart A - General Provisions
 - (b) Subpart B - Initiation of Proceedings
 - (c) Subpart C - Appearance and Participation
 - (d) Subpart D - Presiding Officer
 - (e) Subpart E - Hearing Procedures
 - (f) Subpart F - Administrative Record
 - (g) Subpart G - Initial and Final Decisions
 - (h) Subpart H - Judicial Review
- 3. Initiation Procedures for a Hearing:
 - a. Who may recommend a hearing?
 - (1) Any unit (Team, Division, etc.) within CVM may determine that an issue (safety, efficacy, etc.) before them requires granting an opportunity for a hearing, proposing adverse action on a pending or approved application on relevant scientific issues of fact. If it is decided to recommend a hearing the following steps will be taken:
 - (a) The unit will issue an action memorandum stating the issue(s) and the scientific rationale for its position.
 - (b) The memorandum shall include supporting documents such as raw data, literature or other references, testimonials, etc.

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- (c) The proposal will be forwarded to the appropriate CVM Office Directors for review and comment.
- (2) In addition to the above, a corporation, an individual, or other legal entity may file a petition requesting a hearing on the petitioner's initiative.
- (3) Further, a District Office may recommend a withdrawal of approval action resulting from an investigation which documents significant violations of the conditions of approval, specifically such as the failure to adhere to current Good Manufacturing Practices (cGMPs).
- (4) All FDA employees, other than representatives of the involved Center (and except those specifically designed otherwise), shall be available to advise and participate with the Office of the Commissioner in its functions relating to the hearing and the final decision. This satisfies the regulations regarding Separations of Functions found in 21 CFR §10.55.
- b. Subject Area Responsibility
- (1) Pre-approval NADA issues such as refusal to file or refusal to approve are initiated by the Director, Office of New Animal Drug Evaluation (ONADE).
- (2) There may be some instances where the Divisions of Surveillance and Compliance personnel may become involved when issues of safety and effectiveness concern approved products. The Director, Office of Surveillance and Compliance (OS&C) will initiate all matters pertinent to animal safety and effectiveness. He/she will also address field-initiated recommendations for a withdrawal of approval.
- (3) The Director, Office of ONADE shall initiate all matters pertinent to the human food safety review.
- c. Assessment of Hearing Priority
- The Center Director and Deputy Director, in conjunction with the Office Directors, will set the hearing priorities. Court ordered hearings and human food safety issues will be given the highest priority; animal safety and effectiveness will be given next priority. There may be situations where field initiated actions based on GMP violations may take precedence over all other existing priorities. Also, actions based on section 512(c)(1)(B), refusal to approve, require an expedited hearing action which may change the above priorities.
- d. Assignment of Hearing Manager
- When an Office Director receives a hearing proposal from his/her respective units, he/she shall forward the package with his/her comments and recommendations through the other appropriate Office Directors to the Center

Director and Deputy Director for a decision. If the decision is made to proceed, the file will be referred to Director of the Division of Compliance (HFV-230), through the Office Director, OS&C. The Director of the Division of Compliance will establish a hearing team and select a Hearing Manager. The Hearing Manager shall manage all activities of the hearing proceeding, including the preparation of any formal documents, such as NOOH, EIS, NOH, etc. and shall assist the Office of Chief Counsel throughout the hearing process. The hearing team may consist of staff scientists, regulatory counsel, consumer safety officers, veterinary medical officers, and other support personnel, etc.

4. Responsibilities of Hearing Manager:

a. Central Contact Point

The Hearing Manager shall be the focal point for submission of all data and essential documents pertinent to the Administrative Record. The Hearing Manager shall be responsible for:

- (1) Distributing data and related documents to expert witnesses, consultants, and other staff involved in the overall review of the issue(s).
- (2) Collating and preparing all final documents of Freedom of Information (FOI) responses, Congressional responses and recommendations on the hearing forwarded to him/her.
- (3) Developing the Administrative Record, NOOH, Environmental Impact Statement (EIS), Notice of Hearing (NOH), and other supporting documents for the hearing.
- (4) Making necessary administrative contacts with expert witnesses and consultants.

b. Coordination of Hearings

The Hearing Manager shall coordinate all administrative responsibilities together with the scientific personnel assigned by the appropriate Office Director, in accordance with §12.85. The Hearing Manager will assist in:

- (1) Preparing recommendations and options for use by the Center Director, e.g., to proceed with the withdrawal; to hold a notice in abeyance pending Congressional or other review; to vacate an existing NOOH or NOH; to deny a hearing for lack of scientific issues, or to deny the original request from the CVM staffs;
- (2) Defining scientific issue(s) after a review of the data;

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- (3) Briefing the Center Director and/or the Commissioner (within the constraints of separation of function) on administrative options;
 - (4) Preparing the NOOH, EIS, NOH, Administrative Record, and Evidentiary Record submissions;
 - (5) Coordinating all hiring and payment of experts and/or consultants;
 - (6) Coordinating all interagency functions United States Department of Agriculture (USDA), National Academy of Sciences (NAS), Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH) with respect to the hearing;
 - (7) Responding to Congressional requests for data and
 - (8) Documenting significant decisions in the administrative file including revelation of significant controversies or differences of opinion and their resolution as provided by parts 21 CFR §§10.70 and 10.75.

.c. Scheduling of Assignments

It shall be the responsibility of the Hearing Manager and his/her respective supervisor/manager to:

- (1) Develop, update, and heed the deadlines found in the hearing timetable set up for each hearing.
- (2) After the initial assignment of personnel by the Office Directors, inform the appropriate supervisors of these time constraints, and provide copies of the timetable to them so that they may properly schedule work assignments.
- (3) Insure that the supervisor is contacted, that the personnel are available for the specified period of time (to be confirmed in writing), and that the personnel will return to their units after the specified period.
- (4) Because hearing documents are prepared over a period of many months and often times over a year or more, it will be necessary for the Hearing Manager to keep the appropriate supervisors informed as to when their personnel will be required over this extended period. Personnel will be immediately released to their units after each phase per consultation between the Hearing Manager and the appropriate supervisor.

5. Hearing Manager and FDA/CVM Interactions:

Interaction of individual units within FDA and CVM

- a. FDA Division of Dockets Management (HFA-305)

The Hearing Manager will have CVM responsibility for assisting the Office of Chief Counsel in filing the NOOH, EIS, NOH, Administrative Record, evidentiary record submissions, and other appropriate documents pertinent to the hearing with the Division of Dockets Management (HFA-305) within the applicable time limits allowed by law and/or the regulations.

- (1) All responses received from industry regarding data, extension of time limits, etc., shall be sent from the Division of Dockets Management to the Director, Division of Compliance (HFV-230). The information in turn shall be routed to the Hearing Manager who will distribute it to the assigned scientific personnel and other staffs (GCF-1, etc.) assigned to the hearing.
- (2) The Hearing Manager shall monitor all correspondence from the industry and other groups (Congress, public interest groups, etc.) and all responses to these groups.

b. FDA Office of Legislative Affairs (HFW-10)

The Hearing Manager shall coordinate all activities for CVM necessary to process matters as forwarded by HFW-10 for a response. The Hearing Manager will:

- (1) Obtain the necessary information needed from the appropriate source within CVM or other FDA units.
- (2) Draft a response to HFW-10 for the signature of the Commissioner or other appropriate authority within the constraints of the regulations pertaining to separation of functions.
- (3) In conjunction with other assigned personnel and/or units within FDA, coordinate activities which involve Congressional mandates and which pertain to a hearing.
- (4) Coordinate all responses to inquiries from Congress as they apply to a hearing within the constraints specified above.

c. FDA Office of Chief Counsel (GCF-1)

The Hearing Manager will serve as CVM's primary contact for the attorneys assigned from the Office of the Chief Counsel, and shall assist Chief Counsel in the hearing process.

- (1) Center requests for interpretations on hearing legalities shall be routed through the Hearing Manager.
- (2) Selection of experts and/or consultants for a hearing shall be coordinated

through the Hearing Manager for appropriate Conflict of Interest (COI) review.

- (3) The Hearing Manager shall, where practicable, coordinate meetings held with the scientific staff, attorneys, and/or experts/consultants.

- d. FDA Office of Public Affairs (HFI-40)/CVM Communications Staff (HFV-12). All press releases, talk papers, memos, etc., related to a hearing that will ultimately enter into the public domain shall be reviewed by the Hearing Manager, and if necessary, commented upon by him/her prior to public release. The Hearing Manager will gather information and draft a response when requested by the FDA Office of Public Affairs and/or CVM's Information Officer after consultation with CVM officials and Chief Counsel. After gaining concurrence from the Hearing Manager, these units may then issue a press release, with copies provided to the Hearing Manager.

- e. Other FDA Units

There will be occasions when an Administrative Record must be prepared or purged for FOI purposes, or other reviews must be conducted in a short period of time prior to a hearing proceeding. In some instances the Hearing Manager may have to contact other units within FDA to determine the availability of FOI trained personnel located within the Washington, D.C. area or the various field units within the Office of Regulatory Affairs (ORA). The Hearing Manager shall make all arrangements for housing, per diem, etc., in conjunction with the CVM Office of Management.

- f. CVM Office of Management (HFV-10)

The Hearing Manager shall clear all financial arrangements regarding experts/consultants through the CVM Office of Management (HFV-10) by:

- (1) Requesting Blanket Purchase Agreements (BPAs) for payment of experts/consultants.
- (2) Initiating and monitoring the lodging and travel arrangements for the experts and consultants when they appear for conferences and/or oral testimony before the Administrative Law Judge.
- (3) Coordinating research and/or other contracts resulting from Congressional oversight of a hearing proceeding.

- g. CVM Communications Staff (HFV-12)

The Hearing Manager may request FOI purging assistance/opinions from the FOI Officer, Communications Staff (HFV-12).

- 1) All FOI purged information shall be sent to the Hearing Manager (after

final approval by the FOI Officer) for incorporation into the Administrative Record and submission to the Division of Dockets Management (HFA-305).

- (2) An FOI review will be made of internal memos, letters to the industry, New Animal Drug Applications (NADAs), Master Files (MFs), Investigational New Animal Drugs (INADs), AFs, decimal files, etc., as assigned for purging by the Hearing Manager and in conjunction with the Office of Management and Communications Staff.

h. CVM Environmental Assessment Team (HFV-103)

The Hearing Manager shall coordinate all activities necessary for the preparation of an environmental assessment or EIS, if applicable to a hearing. Coordination required with Environmental Protection Agency (EPA) and other outside agencies shall be through the Hearing Manager in conjunction with the Environmental Science Staff.

i. FDA Economics Staff (HFP-60)

The Hearing Manager shall coordinate the preparation of economic assessments as needed. This may include coordination with outside agencies in conjunction with FDA Economics Staff.

j. CVM Policy and Regulations Team (HFV-6)

The Hearing Manager in conjunction with HFV-6 shall coordinate the preparation of the NOOH, NOH, and other applicable documents for publication in the Federal Register, when required.

k. FDA Regulations Policy and Management Staff (HF-26)/Federal Register Writers Office (HF-27).

The Hearing Manager shall, in conjunction with the Regulations Policy and Management Staff, coordinate the activities necessary to prepare the appropriate documents for publication in the Federal Register. If a project officer is already assigned to an issue in CVM, he/she shall ordinarily appear as the contact person in the Federal Register notice; otherwise, the appropriate supervisor/manager or Hearing Manager shall appear as the contact in the notice.

l. CVM Staff Scientists CVM

The Hearing Manager shall represent CVM, along with the assigned staff scientists in the preparation of all hearing documents, data development, recommendations, etc. The staff scientist will assist the hearing team for a specified period of time necessary to insure complete, integrated, defensible Center position. The staff scientist, under the general guidance of the Hearing

Manager, will assist the Office of Chief Counsel in identifying the issues (safety, effectiveness, etc.) required for the hearing proceedings.

5. References:

The appropriate HHS/FDA/CVM guidelines that may be used in the preparation for a hearing are as follows:

- a. DHHS Project Officers' Contracting Handbook
- b. FDA Staff Manual Guide 2610.1 (6/4/09) Preparing Requisitions for All Contract Actions with an Estimated Value Greater Than the Simplified Acquisition Threshold
- c. FDA Staff Manual Guide 2610.2 (3/19/79) Obtaining Service of Expert or Fact Witnesses.
- d. FDA Staff Manual Guide 2610.7 (6/4/09) Preparing Requisitions for All Contract Actions with an Estimated Value Less Than or Equal to the Simplified Acquisition Threshold

The following references may be found in the CVM Policy and Procedures Manual.

- (1) 1240.2021 - Federal Register Document Activity: Rule-Making Procedures
- (3) 1240.2322 - Intercommunication between CVM and the Office of the Chief Counsel (OCC).
- (4) 1240.2330 - Consultative Reviews and Opinions
- (6) 1240.2500 - Freedom of Information Request.
- (7) 1240.3540 - Withdrawal of Approvals