

GENERAL REVIEW AND ENFORCEMENT POLICIES

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MANAGEMENT OF FORMAL EVIDENTIARY HEARINGS

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

In the past, the Center for Veterinary Medicine has had reason to recommend the issuance of an NOOH on issues of safety and effectiveness of drugs either as a refusal to approve or as a withdrawal of approval. The hearing proceedings that evolved during those years became very cumbersome. The duties of individuals assigned to a hearing team overlapped resulting in duplication of effort, lack of coordination with other units involved, and the issuance of directives from different authorities that often countermanded one another. In conjunction with this the Administrative Practices and Procedures Regulations were often interpreted differently by each team developing hearing documents. The following, therefore, represents an effort to provide a general guide for CVM personnel for all hearing proceedings in the Center. This document describes the responsibilities of CVM personnel selected to assist Office of Chief Counsel in its function as Agency lawyer, identify and litigate the issues giving rise to the Administrative hearing.

1. Purpose:

These procedures have been developed as general guidelines to provide for CVM personnel a central 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 under section 512(d),(e), (m),(3), and (m)(4) of the Act.
  - (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 initiate procedures for 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 their position.
  - (b) The memorandum shall include supporting documents such as raw data, literature or other references, testimonials, etc.
  - (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 violation of the conditions of approval it believes to be serious enough to initiate a withdrawal action.
- (4) All members of FDA, other than representatives of the involved Center (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 310.55.

b. Responsibility for Processing

- (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 (NADE).
- (2) There may be some instances where Surveillance and Compliance (S&C) personnel may become involved when issues of safety and effectiveness concern approved products. The Director, Office of S&C will process post-marketing issues concerning animal safety and effectiveness. He/she will also address field-initiated recommendations for a withdrawal of approval.
- (3) The Director, Office of NADE shall initiate all issues pertinent to the human food safety review.

c. Assessment of Hearing Priority

Priorities for the development of issues for one hearing over another will be decided by the Office Directors in conjunction with the Center Director and Deputy Director. 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 Good Manufacturing Practices (GMP) violations may take precedence over all other existing priorities. Also, actions based on section 512(c)(1)(B), refusal to approve violation, require an expedited hearing action which may change the above priorities.

d. Assignment of Hearing Manager

When a CVM 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 the Office Director for S&C for assignment to the Director of the Division of Compliance (HFV-230) for the establishment of a hearing team and selection of a hearing Manager. Thus, the Hearing Manager enters into the hearing process at the beginning prior to the preparation of any formal documents, such as NOOH, EIS, NOH, etc. From this point on, the Hearing Manager shall on behalf of CVM manage all activities of that hearing proceeding and shall assist the Office of Chief Counsel in proceeding to the hearing. Hearing managers will be assigned from the Division of Compliance, HFV-230.

4. Responsibilities of Hearing Manager:

a. Central Contact Point

In conjunction with assisting the Office of Chief Counsel, 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 staffs involved in the overall review of the issue(s).
- (2) Collating and preparing all final documents of FOI responses, Congressional responses and recommendations on the hearing issue(s) forwarded to him/her.
- (3) Under his/her leadership and in conjunction with the appropriate staffs involved, developing the Administrative Record, NOOH, EIS, 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 hold all coordination and hearing management responsibilities for CVM. In conjunction with the scientific personnel assigned by the appropriate Office Director, 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;
- (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 hiring and payment of experts and/or consultants;
- (6) Coordinating all interagency functions (USDA, NAS, CDC, NIH) with respect to the hearing;
- (7) Responding to Congressional requests for data on the issue(s), when requested; 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 Team Leader 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 be released to 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 CVM/FDA Interactions:

Interaction of individual units within FDA, CVM.

a. Dockets Management Branch (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 Dockets Management Branch (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 Dockets Management Branch 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. Associate Commissioner for 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. 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 development of issue(s) pertinent to a hearing.

- (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 Press Relations Staff (HFI-40)/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 Press Relations 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 release on the issue, with copies issued 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 ascertain the availability of FOI trained personnel located within the Washington, D.C. area or the various field units (ORA). The Hearing Manager shall make all arrangements for housing, per diem, etc., in conjunction with the CVM Administrative Services Branch.

f. CVM Administrative Staff (HFV-15)

The Hearing Manager shall clear all financial arrangements regarding experts/consultants through the CVM Administrative Staff (HFV-15) by:

- (1) Requesting Blanket Purchase Agreements (BPAs) for payment of experts/consultants for hearings through his/her respective Team Leader.
- (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. 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 Dockets Management Branch (HFA-305).

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

h. Environmental Assessment Team (HFV-145)

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 EPA and other outside agencies shall be through the Hearing Manager in conjunction with the Environmental Science Staff.

i. FDA Economic Assessment Group (HFP-61)

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

j. 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. 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 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 Team Leader or Hearing Manager shall appear as the contact in the notice.

l. Staff Scientists (CVM)

The Hearing Manager shall represent CVM, along with the staff scientists assigned by the appropriate Office Director within CVM in initiating the preparation of all hearing documents, data development, recommendations, etc. The scientist is to be assigned to 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. HHS H-79-1 (6/14/79) Obtaining Procurement and Contract Services.
- b. HHS Negotiated Contracting Process, A Guide for Project Officers.
- c. FDA Staff Manual Guide 2610.2 (3/19/79) Obtaining Service of Expert or Fact Witnesses.

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

- (1) 1240.2021 - Federal Register Document Activity.
- (2) 1240.2320 - Communications and Liaison with other Centers and Agencies.
- (3) 1240.2322 - Intercommunication between CVM and the Office of the Chief Counsel (OCC).
- (4) 1240.2330 - Consultative Reviews and Opinions.
- (5) 1240.2410 - Environmental Impact Consideration for Industry-Initiated Actions.
- (6) 1240.2500 - Freedom of Information Guidelines.
- (7) 1240.3540 - Withdrawal of Approvals.