GENERAL PROCEDURAL POLICIES

PROCEDURES FOR RESOLVING SCIENTIFIC/DATA DISAGREEMENTS WITHIN CVM

In the review of ANADAs, NADAs, DERs or proposed compliance actions related to the regulation of animal products, there may be differences of opinion regarding the interpretation of scientific data or appropriate courses of action. When such disagreements occur, it is necessary to follow appropriate procedures for resolving them. Center management shall create an atmosphere in which consultation-and open discussion on controversial issues are encouraged. Managers should create an atmosphere of openness, trust, and respect for individuals' views in resolving differences. Behaviors that are counter-productive to the creation of a desirable work culture are, unacceptable. In particular, retribution and/or retaliation against employees that follow the dispute resolution process described in this procedure will not be tolerated. It is the responsibility of all those involved to ensure employees are protected from retaliation by their supervisors, peers, Center leadership, and others when engaging in this process.

Informal methods using good management practices for resolving conflict should be employed prior to institution of the more formal procedures described below. (See CVM Program Policy and Procedures Manual (PPM) 1240.2120 - Product Manager (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046330.pdf.) A number of avenues are available to discuss and resolve scientific differences and enhance decision-making by utilizing the channels of supervision or review. These include meetings within the review Team(s) and at the Division level, review by established internal groups and if necessary at the level of the Office Director. If informal attempts fail, the formal procedures for resolving disagreements are set forth in 21 CFR 10.70 and 21 CFR 10.75.

When a CVM employee believes that an ongoing issue related to a science or policy decision made by the Center is important because of its potential impact on public or animal health, and that it is either not being addressed or not being given adequate consideration through normal supervisory channels, the employee may request informal internal review by the Center Leadership Team (CLT). (See CVM PPM 1240.2115 - Procedures for Internal CVM Review of Science or Policy Issues Related to Significant Decisions of High Impact (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/ucm046329.pdf .) Additionally, disagreements of sufficient immediacy and scale of impact on public health may 'opt-up' to the Center Director in order that she/he may make a decision on the matter within a condensed timeframe.

1. **Purpose:**

   This document outlines the procedures to be followed to resolve disagreements arising from differences of opinion regarding the interpretation of data or the appropriate course of action for the Center to pursue.

2. **Documentation of Decision:**

a. The documentation of decisions made by employees of the Food and Drug Administration (FDA) is addressed in 21 CFR 10.70 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.70).

b. An administrative file (e.g., ANADA, NADA, FAP, INAD, DER) shall be kept and must contain documentation of the bases for recommendations and decisions. This documentation shall include signed reviews, memoranda, letters, opinions of consultants, and all other written documents pertinent to the matter.

c. The documentation shall reveal any significant controversies or differences of opinion and their resolution.

EXAMPLE:

If there is a difference of opinion concerning the animal safety data in an NADA, the administrative file would consist of all written documents pertaining to the animal safety data.

d. It is the responsibility of each CVM employee to assure that each administrative file is complete.

e. Employees who remove, alter, or inhibit the placement of documents into the administrative file, will be subject to disciplinary action.

3. **Review of Decisions:**

a. The internal Agency review of decisions is addressed in 21 CFR 10.75 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.75).

b. Any decision made by an FDA employee is subject to review by the employee's supervisor. The review may be initiated by the employee or the employee's supervisor, persons from outside the Agency, or individuals with duly promulgated delegations of authority.

c. Differences of opinion should be resolved at the lowest organizational level possible.

To assure prompt resolution of a disagreement, a written response from the responsible deciding official at each level of management must be issued within 30 calendar days and placed in the administrative file. Copies of the written review(s) will be provided to each principle in the disagreement.

EXAMPLE:

If the differences of opinion cannot be resolved between the reviewer and his/her supervisor, then the Division Director has the responsibility for resolving the

differences. If the various levels of management disagree with the reviewer's position on a particular matter then they shall submit their comments in writing to the administrative file within 30 calendar days of receiving the disagreement. A copy shall be sent to the reviewer(s).

d. The Center Director or the Commissioner shall personally review matters that cannot be resolved at lower levels.

(1) The review of any decision shall be based on information in the administrative file.

(2) In a situation where the administrative file is unclear, there shall be oral communication between the disagreeing parties. The final decision shall be reduced to writing and placed in the file.

(3) When new information is added to the file, the matter shall be returned to the appropriate lower level within the Center for re-evaluation.

(4) To assure the prompt resolution of a disagreement, a written response from the responsible deciding official must be issued within 30 calendar days. Copies of the written review will be sent to each principle in the disagreement.

(5) After the Center-level processes have been properly followed and exhausted (which must include a written opinion by the Center Director) and the employee is not satisfied with that written decision, he/she should be advised of and may consider elevating the dissent to the Agency level as per Staff Manual Guide (SMG) 9010.1 Scientific Dispute Resolution (http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm215422.htm) at FDA. This process is intended to address serious scientific dissents that could have significant negative impact on public health. The initiator/employee must elevate the scientific dissent issue to the agency appeals process within 10 days of receiving the written opinion rendered by the Center Director.

4. **Role of the CVM Ombudsman**

The employee can choose to contact the Ombudsman at any time to discuss the issue(s) and the appropriate options for resolution that are available including these procedures. As is consistent with the Ombudsman's role in conflict resolution, any communication between the employee and the CVM Ombudsman, is with few exceptions, confidential at the employee's request (See Complaints/Dispute Resolution Process Confidentiality (http://www.fda.gov/AboutFDA/CentersOffices/CVM/CVMOmbudsman/ucm079977.htm)).

After discussion of the science or policy-related issues, the CVM Ombudsman will explore options with the employee as to how to proceed. The Ombudsman will likely recommend that the employee follow the established managerial levels in the chain of command for this formal process and will advise and council the him /her on the appropriate use of the procedures outlined in CVM PPM 1240.2115 - Procedures for Internal CVM Review of Science or Policy Issues Related to Significant Decisions of High Impact (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresMa

nual/ucm046329.pdf) and the Agency's SMG 9010.1 http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm215422.htm) for internal scientific dispute resolution (SDR).

VERSION HISTORY

March 3, 2005 – Original version

December 5, 2005 – Minor Revisions

January 23, 2009 – Office of the Director revised and updated to comply with the mandatory requirements and to make reference to the new Agency-level process.

June 27, 2011 – Added full text links to document

July 28, 2011 - Minor changes--added the word "calendar" to 30 days in the last paragraph under 3.c. on page 2 and the first paragraph on page 3;
Added link to SMG 9010.1 in d.(5) on page 3;