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. Informal methods using good management practices for resolving conflict should be employed prior to institution of the more formal procedures described below. (See CVM Guide 1240.2120.) Center management shall create an atmosphere in which consultation-and open discussion on controversial issues are encouraged. If informal attempts fail, the formal procedures for resolving disagreements are set forth in 21 CFR 10.70 and 21 CFR 10.75.

1. **Purpose:**

   This guide 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.

   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

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.

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. 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 days. Copies of the written review will be sent to each principle in the disagreement.