Product Manager

Investigational New Animal Drug Applications and New Animal Drug Applications (original and abbreviated) for specific drug products are the responsibility of the division to which the initial assignment is made. The division director is ultimately the product manager for each document assigned to his/her division. The assignment of specific documents to individual product managers within a division is made at the discretion of the division director.

1. **Purpose:**

   This document defines the assignment of responsibility where interdivision review of applications is involved.

2. **Assignment to Divisions:**

   a. The Document Control Unit (HFV-199) will assign new documents to the appropriate division according to animal class (food/non-food) and pharmacologic category (production/therapeutic) unless directed otherwise.

   b. When a document involves multiple classes or pharmacologic categories, the Director, Office of New Animal Drug Evaluation (ONADE), (HFV-100) or his/her delegate will make the assignment to the appropriate division, taking into consideration:

      (1) Workloads of the divisions involved;

      (2) Dominance of claims;

      (3) Use patterns (claims) of the product; and

      (4) Dosage form of the product.

   c. Once the assignment is made, that division becomes the permanent product manager. Only the ONADE Director can make a reassignment of the product. The following are examples of situations that could cause a reassignment:

      (l) A document involving only non-food animals is later supplemented to provide for use in a food animal.

      (2) The document becomes dominated (through supplements) by a use other than the original use

      (3) The workload of the original division is out of proportion to those of other divisions.

3. **Handling of Correspondence:**

The handling of all future correspondence concerning a document, whether it be general or a specific supplement, will be handled by the division to which the document has originally been assigned unless agreed otherwise by the responsible division directors.

EXAMPLE:

NADA providing for the use of a drug in dogs has been assigned to the Division of Therapeutic Drugs for Non-Food Animals (DTDNFA). A supplement to the original application is received that proposes a use in cattle. This supplement is forwarded to the DTDNFA which is totally responsible and accountable for it. It is the administrative responsibility of the DTDNFA to review all aspects of the cattle supplement, except for the efficacy and safety data, human food safety data, and proposed labeling. This data will be forwarded to the Division of Therapeutic Drugs for Food Animals (DTDFA) for consultative review. All administrative aspects of the documents, such as the drafting of the summaries and letters to the firm, are the responsibility of the DTDNFA.

4. **New Animal Drug Applications:**

The procedures below cover original and abbreviated new animal drug applications.

a. Generally, there shall be one NADA for each specific dosage form regardless of:

(1) number of species involved;

(2) various concentrations of the specific dosage; and

(3) any requirement for species specific labels.

b. Any deviation from this policy must be approved by the Director for ONADE

5. **Investigational New Animal Drug Applications:**

Separate INADs are permitted for each species. When more than one division is involved in the processing of INADs for the same drug (product), any correspondence and meetings with the sponsor will be coordinated with all the involved divisions.

6. **Resolution of Conflicting Opinions**:

Center managers are expected to 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 document 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.

In the event the product manager receives a consulting review which contains recommendations or statements to which he/she disagrees, informal methods using good management practices for resolving conflicts should be employed. 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 which may include review by established internal groups. To assure the prompt resolution of a disagreement a written response from the product manager must be issued within 30 days. Copies of the written review will be sent to each principle involved in the disagreement.

A record of any significant controversies or differences of opinion and their resolution should be entered in the product's administrative file as per 21 CFR 21.70. If informal methods fail, the formal procedures for resolving disagreements should be employed and are addressed in CVM PPM 2140.2110 (Procedures for Resolving Scientific/Data Disagreements within CVM).

7. Role of the CVM Ombudsman

An employee can choose to contact the Ombudsman at any time to discuss the issue(s) and the appropriate options for resolving internal science/policy issues that are available. 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/cvm/complaints.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 take the issue to the next level in the chain of command, if they have not already done so. The Ombudsman may also advise him/her on the appropriate use of the SDR procedures outlined in CVM PPM 1240.2110 (Procedures for Resolving Scientific Data/Disagreements within CVM) and 1240.2115 (Procedures for Internal Review of Science or Policy Issues Related to Significant Decisions of High Impact).

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 the Staff Manual Guide (SMG) 9010.1 Scientific Dispute Resolution 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.

Version History

August 11, 1993 – Original version
August 26, 1997 – 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.