GENERAL PROCEDURAL POLICIES

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 guide 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:

An 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**:

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 record of any significant controversies or differences of opinion and their resolution should be entered in the product's administrative file.