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GENERAL REVIEW AND ENFORCEMENT POLICIES

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PROCESSING ORIGINAL INVESTIGATIONAL  
NEW ANIMAL DRUG APPLICATIONS

1. Purpose:

This guide identifies the procedures to follow for processing original investigational new animal drug (INAD) applications.

2. Distribution of Investigational New Animal Drug Applications:

- a. The proposed INAD application is received by the Document Control Unit (DCU), which date stamps the submission, records its receipt, cross-checks records to verify that it is an original submission, prepares a draft acknowledgement letter with a tentative INAD number, and enters pertinent information into the STARS system. The submission is then hand-carried to the appropriate Division Director, who performs an informal cursory review. If the submission basically complies with 21 CFR 511.1, the Division Director initials the pink copy of the acknowledgement letter and returns the file to DCU and the acknowledgement letter is issued. If the submission contains major deficiencies, the Division Director will instruct DCU to convert the file to a General Correspondence (GC). DCU will then officially forward the file (INAD or GC) to the appropriate Division Director through Document Tracking (HFV-103).
- b. The Division Director assigns the INAD or GC to the appropriate responsible team and notifies DCU of this assignment.
- c. The Team Leader then assigns the INAD or GC to a specific primary reviewer.

3. Responsibilities of the Primary Reviewer:

- a. The primary reviewer determines whether or not the submission contains adequate information to warrant a review and identifies those areas in which it is deficient. If the reviewer has questions regarding the submission, the sponsor may be requested to clarify the information submitted or to provide additional information. This request may be made by telephone or by letter. Letters requesting additional information are

prepared for the Division Director's signature.

- b. Once the reviewer has determined that the submission is complete enough to justify a review, copies of the submission should be forwarded to other individuals/offices for appropriate consulting reviews. This should be accomplished within two working days of receipt of the INAD by the reviewer. Requests for consulting reviews by individuals/offices outside the reviewer's Division must be routed through Document Tracking (HFV-103).
  - (1) If the submission contains a protocol which requires a statistical consulting review, according to NADE policy, it should be forwarded to the Biometrics Team.
  - (2) Any human safety data or any request for authorization to slaughter investigational animals for food purposes or to use edible products from the investigational animals must be forwarded to HFV-144 for toxicology and/or chemistry review. Additional requests by INAD sponsors or individual investigators need not be forwarded to HFV-144 if an adequate number of animals remains from those originally authorized, and the subsequent requests (dosage, directions for use, route of administration, etc.) are covered by the initial authorization.
  - (3) If the primary reviewer determines that other input (chemist, parasitologist, veterinarian, nutritionist, environmental staff etc.) is needed the submission should be forwarded to the appropriate individual/Team.
- c. When all of the consulting reviews have been returned, the primary reviewer prepares a document summary for the INAD. This should include reference to all consulting reviews, as well as the reviewer's own comments on the application.
- d. After completing the document summary, the primary reviewer prepares a letter(s) to the sponsor.
  - (1) If the INAD has deficiencies, or if other comments are indicated, the sponsor should be notified in an acknowledgement letter signed by the Division Director.
  - (2) If authorization to market edible products of treated animals is to be granted,

the primary reviewer prepares an authorization letter. The authorization letter should include an adequate number of animals to meet NADA requirements or meet the needs of an individual investigator. The authorization letter is prepared for the signature of the Director, Office of New Animal Drug Evaluation.

- (3) If both an authorization and other comments are to be forwarded to the sponsor, the reviewer should prepare two separate letters.
  - e. After preparing the document summary and the appropriate letter(s), the primary reviewer forwards the entire package (jackets, consulting reviews, document summary and letter) to the Team Leader.
4. Responsibilities of the Team Leader:
- a. Reviews and evaluates the conclusions of all reviewers.
  - b. Checks the materials submitted for completeness, accuracy, and conformance with regulations and policy.
  - c. Either concurs with the issuance of the letter(s) as prepared or returns the entire package to the primary reviewer for discussion or revision.
  - d. When all outstanding issues have been resolved and/or revisions have been made, initials the pink copy of the letter(s), and forwards the entire package to the Division Director.
5. Responsibilities of the Division Director:
- a. Reviews and evaluates the conclusions of the reviewers and the Team Leader.
  - b. Either concurs with the issuance of the letter(s) as prepared or returns the entire package to the Team Leader for discussion or revision.
  - c. When all outstanding issues have been resolved and/or revisions have been made, initials the pink copy of the letter(s), signs the acknowledgement letter to the sponsor (if there is one), and forwards the entire package to HFV-102.
6. Responsibilities of HFV-102:

- a. Performs an overall review for consistency with current scientific and administrative policy of NADE and the Center.
- b. Either concurs with the issuance of the letter(s) as prepared or returns the entire package to the Division Director for discussion or revision.
- c. When all outstanding issues have been resolved and/or revisions have been made, initials the pink copy of the letter(s), and either forwards the entire package to the Director, Office of New Animal Drug Evaluation for signature of an authorization letter, or forwards the entire package to Document Tracking (HFV-103) for issuance of an acknowledgement letter and return of the documents to DCU for filing.

Note: Authorization letters are not issued for investigational new animal drugs for non-food animals.

Authorization letters for aquaculture drugs are not sent to USDA/FSIS, and may contain information other than authorization subject matter.