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GENERAL REVIEW AND ENFORCEMENT POLICIES

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**PROCESSING AMENDMENTS TO AN  
INVESTIGATIONAL NEW ANIMAL DRUG APPLICATION**

Amendments to investigational new animal drug applications (INADs) may consist of any of the following types of information:

- a. response to a letter requesting additional information;
- b. protocols for collecting effectiveness, animal safety, or human safety data;
- c. trial notifications which are in accordance with a previously issued authorization;
- d. requests for amended authorization;
- e. submission of human safety data;
- f. submission of dose determination data; or
- g. requests for meetings.

1. Purpose:

This guide identifies the procedures to be followed for processing amendments to INADs.

2. Distribution of Amendments:

- a. An amendment is received by the Document Control Unit (DCU), which date stamps it, records its receipt, and enters pertinent information into the submission tracking and reporting system (STARS). The amendment is then delivered, through Document Tracking, to the responsibleTeam (HFV-103).
- b. DCU sends one copy of each trial notification to the Bioresearch Monitoring Program Staff (HFV-234) before delivering the file to the responsibleTeam.
- c. DCU logs into the STARS all INAD related submissions, including letters reporting final disposition of animals, letters reporting the intended date and place of slaughter, and USDA slaughter reports.

3. Processing of Amendments:

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- a. TheTeam Leader assigns the document to the primary reviewer or other responsible individual (e.g., consumer safety officer, consumer safety technician, or applications examiner).
  - b. The primary reviewer/other individual:
    - (1) Determines the nature of the amendment and proceeds with the appropriate action. Amendments containing requests for amended authorization, protocols, safety data, or dose determination data, for which review is required, are treated in the same manner as an original INAD. (See Guide 1240.3010.)
    - (2) Processes trial and slaughter notifications:
      - (a) Reviews trial and slaughter notifications to determine:
        - (i) If the sponsor has an authorization letter to cover slaughter of the animals or use of edible products (milk, eggs).
        - (ii) If the details of the trial are within the conditions of the authorization letter. If they are not, prepares a denial letter for the Division Director's signature.
      - (iii) If the firm is requesting a waiver of the requirements for notification of date and place of slaughter.
        - (b) Notes the number of treated and control animals in the comments section of this form.
        - (c) Files no reply (FNR), if appropriate, on the submission. If the investigational new animal drug is being used in food-producing animals, sends a copy of each trial notification for that drug to USDA/FSIS.
    - (3) Following completion of all reviews, prepares a letter to the sponsor, if necessary. Forwards the submission, all documentation, proposed letter, and open volume of the INAD to theTeam Leader. Amended authorization letters are signed by the Director, Office of New Animal Drug Evaluation. All other letters are signed by the division director. The procedures for reviewing and forwarding amendments to INADs are the same as those found in Guide 1240.3010 for original INADs.
  4. Notification of Intent to Slaughter and Slaughter Reports:

Unless the sponsor requests and receives a waiver of the requirements, the sponsor must notify CVM and USDA/FSIS of the date and place of slaughter at least ten days prior to shipment of the investigational animals for slaughter. Such notice, as well as slaughter reports received from USDA, are placed in the appropriate INAD. These reports are logged to the responsibleTeam by DCU and should be reviewed by the individual in the responsibleTeam designated by the Team Leader. This individual notes any adverse effects or other useful information. Any adverse effects should also be brought to the attention of the primary reviewer. The individual then enters the appropriate action ("File No Reply"), initials, dates the submission, and forwards it to DCU.