ROUTING A REQUEST TO OBTAIN A REVIEW OF AN INAD, JINAD, ANADA, NADA, OR VMF SUBMISSION

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I. PURPOSE

This document describes the standard procedures for routing a request for a review (consult) of an Investigational New Animal Drug (INAD) file, a Generic New Animal Drug (JINAD) file, an Abbreviated New Animal Drug Application (ANADA), a New Animal Drug Application (NADA), or a Veterinary Master File (VMF) submission.

II. REQUESTING A CONSULT

Following the determination that an application or submission is acceptable for review, the reviewer makes an assessment of what consults they need and routes the submission or pertinent parts of the submission to the appropriate team for review.

NOTE: Requests for consults should be sent to the appropriate Division or Team. In the "Action Requested" section of the Review Request and Movement Form clearly indicate what should be reviewed.

III. GENERAL RULES GOVERNING A REQUEST FOR A CONSULT

The following guidelines concern requests for a consulting review:

A. When to prepare the request

The request for a consult should be prepared within five days after the submission is date-stamped by the Document Control Unit (DCU). The requester should keep in mind the current ONADE timeframes so that the consulting reviewer receiving the request has adequate time to complete it.

B. How to request the consult

The request for a consult is logged through the DCU using the Submission Tracking and Retrieval System (STARS). The request for a consult is sent to the specific Division/Team identified by the primary reviewer.

C. When the consult is complete

When the consult is complete, the consulting reviewer sends it back to the primary reviewer in paper (hard) copy through the DCU. For electronic submissions, consults should be returned through ONFI (see P&P 1243.3029). The consulting reviewer sends the electronic file or files that are the electronic copy of the consulting review to the CVM ONADE Records mailbox.

IV. ROUTING A REQUEST FOR A CHEMISTRY, MANUFACTURING, AND CONTROLS CONSULT

A request for a Chemistry, Manufacturing, and Controls (CMC) consult is routed to the appropriate Team in the Division of Manufacturing Technologies as follows:

- If the application pertains to a medicated article or feed (i.e., Type A medicated article, Type B medicated feed, and Type C medicated feed) or topical, the submission is routed to the Feed/Topical Team.

- If the application pertains to a sterile drug product, the submission is routed to the Antimicrobial Team.

- If the application pertains to an oral dosage form (i.e., tablet, solution, etc.), the submission is routed to the Chemotherapeutic Team.

- If the application pertains to a biological/biotechnological or competitive exclusion derived drug product, a Minor Use Minor Species drug product, or a soluble powder, the submission is routed to the Biotherapeutic Team.

- If the application pertains to a generic drug product (no matter the dosage form), the submission is routed to the Generic Team.

V. ROUTING A REQUEST FOR A HUMAN FOOD SAFETY CONSULT

If a drug is intended for use in food-producing animals, the submission or pertinent parts are sent for a consult to the Division of Human Food Safety.

A. Toxicology data

If only toxicology data (e.g., general toxicology, genetic toxicology, and reproductive toxicology studies) are included in the package, send the request to the Toxicology Team.

B. Residue data

If a submission has only residue data (e.g., studies and summaries of studies pertaining to presence and identification of residues in edible tissues, metabolism studies in the target species, comparative metabolism studies in the toxicological species, residue depletion studies in the food-producing animal, analytical methods for detection or identification of residues in the target animal), send the request for review to the Residue Chemistry Team.

C. Antimicrobial resistance

If only antimicrobial resistance data (e.g., protocols, study reports, supporting literature, etc.) are included in the package, send the request to the Microbial Food Safety Team. Send all applications for new antimicrobials or changes to previously approved antimicrobial drugs to the Microbial Food Safety Team.

D. Multiple food safety components

If a submission contains data/studies applicable to more than one team in the Division of Human Food Safety, send the request for a consult to the Division of

Human Food Safety. They will route it as appropriate within the division. This includes food use authorizations.

E. User safety

User safety consults are not automatically routed to the Division of Human Food Safety. Primary reviewers are to examine this information themselves and request a consult, if needed.

VI. ROUTING A REQUEST FOR AN ENVIRONMENTAL CONSULT

All applications or petitions requesting agency action require the submission of an environmental assessment (EA) or a claim of categorical exclusion.[1]

An INAD, JINAD, ANADA, or NADA submission may contain environmental study protocols, environmental study reports, an environmental assessment, or a claim for a categorical exclusion from preparing an EA.

A. Request a consult

If a submission contains environmental protocols, study reports, or similar information, send a consult request to the Environmental Safety Team for review.

B. Categorical exclusions

If a submission contains a claim for categorical exclusion from preparing an EA, generally a primary reviewer will review it following the guidance contained in P&P 1243.7220. If the primary reviewer identifies extraordinary circumstances or determines that the claim for categorical exclusion requires review or concurrence by the Environmental Safety Team, they will send a consult request to that team.

VII. ROUTING A REQUEST FOR A STATISTICAL CONSULT

If a statistical consult for an INAD, JINAD, ANADA, or NADA submission is needed, it should be routed to the Biometrics Team.

[1] See 21 CFR 25.33.

A statistical consult differs from most other consults because it is not generally intended as a stand-alone review. The Biometrics Team may provide a review on specific statistical aspects of a single study or an analysis of pooled studies. Prior to the statistical consult, the primary reviewer should ensure that the study is generally acceptable and that the measurements selected or proposed are appropriate.

In practice, a copy of the submission is forwarded to the Biometrics Team (and placed in the queue). The reviewer in the Biometrics Team prepares a review including a transmittal section and sends it to the requestor of the review. If the reviewer requesting the statistical consult finds during the course of his review that the submission is not acceptable, he meets with the Biometrics reviewer to discuss whether the Biometrics consult should continue.

VIII. ROUTING A REQUEST FOR A LABELING CONSULT

The primary reviewer sends a request for a labeling consult for all labeling M submissions, original and supplemental NADAs, and original and supplemental ANADAs to:

- Division of Surveillance and Division of Animal Feeds, Medicated Feeds Team (if labeling is for Type A medicated articles and/or Type B and C medicated feeds).

- The appropriate Team in the Division of Manufacturing Technologies as stated in section IV of this P&P.

- Division of Human Food Safety (if it is a food animal drug; for ANADAs, an informal consult should be made before submitting a formal request for a consult).

IX. ROUTING A REQUEST FOR A PHARMACOKINETICS CONSULT

If a submission contains information pertaining to pharmacokinetics (PK) of the new animal drug (e.g., PK studies, proposed plasma drug concentration sampling times), a pharmacokinetics consult may be requested.

Upon receipt of the submission and determination of the need for a pharmacokinetics consult, the primary reviewer should send a request for consult to the appropriate pharmacokinetics expert.

X. ROUTING A REQUEST FOR A RISK ASSESSMENT CONSULT

When needed, a request for a risk assessment consult is routed to the Risk Assessment Team.

XI. REFERENCES

Code of Federal Regulations (Title 21)

Part 25 – Environmental Impact Considerations

§25.33, Animal drugs

CVM Program Policy and Procedures Manual

1243.3029, Closing out a consulting review

1243.7220, Environmental review: evaluating claims of categorical exclusion for actions relating to new animal drugs

XII. VERSION HISTORY

November 16, 2001 - Original version

December 19, 2007 – Version updated to remove sections now in the approval package P&P 1243.3800. Also reformatted and brought up to date regarding processing of labeling supplements.