INVESTIGATIONAL FOOD-USE AUTHORIZATIONS: THE ROLE OF THE DIVISION OF HUMAN FOOD SAFETY REVIEWER

I. PURPOSE

This document describes the role of the Division of Human Food Safety (DHFS) in the review of food-use authorization requests.

It explains:

- How to route requests for food-use authorizations;
- The information the DHFS evaluates when responding to a request for a food-use authorization;
- The response the DHFS provides to a request for a food-use authorization, including the format for the Authorization Table;
- How and when to make modifications to the structure or content of the Authorization Table.

See P&P 1243.4040 for information on final processing of the investigational food-use authorization request and for examples of response letters and letter templates.

II. HOW ARE FOOD USE AUTHORIZATIONS ROUTED TO DHFS?

DHFS receives requests for food-use authorizations for evaluation as STARS consulting reviews from the primary review groups. See P&P 1243.3200 for information on routing between divisions within the ONADE and P&P 1243.4040 for the role of the primary review group(s) in the food-use authorization process. Once completed, DHFS routes the consulting review back through STARS from the DHFS to the primary review group that requested the human food safety review and recommendation (see P&P 1243.3005, Creating Clean Electronic Files; P&P 1243.3009, Format and Style Conventions for Reviews and Submission Summaries; P&P 1243.3029, Closing out a consulting review).

III. WHAT INFORMATION DOES DHFS EVALUATE FOR A FOOD-USE REQUEST?

The DHFS uses the data and information available to evaluate the safety of residues of the investigational new animal drug to the human consumer. The primary issues addressed in any human food safety evaluation of a food-use authorization request are toxicology, residue chemistry, and when the request involves bacteria (e.g., competitive exclusion products or probiotics, antibiotics, and other drugs with antibacterial actions), microbial food safety.

IV. WHAT WILL DHFS PROVIDE IN THEIR CONSULTING REVIEW FOR A REQUEST?

The DHFS provides recommendations to the primary review group in a consulting review. The ONADE either grants or denies an authorization.

A. Food Use Authorization Granted

When the DHFS concludes that the request for a food-use authorization is appropriate, the consulting review from the DHFS provides, as part of the "Transmit to Sponsor" section, the conditions of the authorization in a table. The authorization letter to the sponsor conveys the conditions of the food-use authorization. Where applicable, the authorization also identifies the information needed to further shorten the investigational preslaughter withdrawal or milk discard time.

When the DHFS has additional proprietary comments to convey to the sponsor, identify these comments clearly in the "Transmit to Sponsor" section of the consult review for inclusion in an Acknowledgement letter (see P&P 1243.4040).

B. Food Use Authorization Denied

When the request for a food-use authorization does not contain sufficient information to complete an evaluation, the DHFS recommends denial of the request for the food-use authorization until the requested information is provided. Include the information that the DHFS needs to continue its evaluation of the food use authorization in the "Transmit to Sponsor" section of the consulting review.

V. AUTHORIZATION TABLE FORMAT AND CONTENT

When a food-use authorization is appropriate, DHFS provides an authorization table. An example table is included as Appendix 1. The DHFS, except where noted below, completes the table for inclusion with the response to the sponsor. The guiding principle when filling out the authorization table is to convey clearly and concisely all necessary information associated with the conditions of the authorization.

VI. MODIFYING THE STRUCTURE OF THE AUTHORIZATION TABLE

The construction of the authorization table assumes the simplest scenario: one investigational drug, one species, one class, one permitted dosing regimen. However, some requests for food-use authorizations are more complex. When necessary, modify the basic table structure to accommodate the increased complexity for multiple species, dosage forms, or dosing regimens within the same authorization. Alternatively, prepare separate authorization tables in response to a single food-use authorization request to describe complex dosing regimes or to address concerns for positive control or vehicle control treatments. The nature of some requests may require the establishment of another (J)INAD file.

VII. MINOR CHANGES TO THE CONTENT OF THE AUTHORIZATION TABLE

Sometimes the authorization table requires revision after the consulting review returns to the requesting primary review group. When minor revisions to the authorization table are needed, the primary reviewer discusses the proposed changes with the reviewer in the DHFS. Summarize these discussions in the primary reviewer's "Submission Summary."

VIII. REFERENCES

CVM Program Policy and Procedure Manual

1243.3005 - Creating Clean Electronic Documents

1243.3009 - Format and Style Conventions for Reviews and Submission Summaries

1243.3029 – Closing Out a Consulting Review

1243.3033 - Permissible STARS Action Codes for STARS Submissions

1243.3200 - Routing a Request to Obtain a Review of an INAD, JINAD, ANADA, NADA, or VMF Submission

1243.4040 - Investigational Food-Use Authorizations: The Role of the Primary (AA) Review Division

1243.7220 - Environmental Review: Evaluating Claims of Categorical Exclusion for Actions Relating to New Animal Drug

IX. VERSION HISTORY

March 31, 2009 – Original version

April 7, 2009 – Revised to update authorization table (i.e., change milk discard period to milk discard time and change drug identity to drug ingredient/feed identity, add feed ingredient identity, and remove rendering).

APPENDIX 1 – AUTHORIZATION TABLE

DRUG IDENTITY/FEED INGREDIENT IDENTITY	Enter the name of the investigational drug or feed ingredient and prominent excipients
Dosage Form	Enter the physical description of the investigational drug product (*e.g.*, Type A medicated article)
SPECIES	Enter the broad common name
Class	Enter when the "Species" entry does not provide an adequate description of the investigational animals
Number of Animals	Enter the number of additional investigational animals being authorized for food use
PERMITTED DOSING REGIMEN	
Maximum Dose (or range)	Enter the maximum dose (or dose range) of the investigational new animal drug(s
Route of Administration	Enter the method by which the investigational new animal drug is introduced into the animal.
Frequency and Duration of Dosing	Enter the maximum timing (frequency) and length (duration) of the investigational treatment.
MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD	Enter the length of time from the last administration of the investigational drug until the treated animals can be slaughtered for human or animal food
MINIMUM INVESTIGATIONAL MILK DISCARD TIME	Enter the length of time from the last administration of the investigational drug until the milk from treated animals can be used as human or animal food
OTHER RESTRICTIONS OR CONDITIONS	Enter any other restrictions on the use of the investigational drug or investigational animals