INVESTIGATIONAL FOOD-USE AUTHORIZATIONS: THE ROLE OF THE PRIMARY (AA) REVIEW DIVISION

I. PURPOSE

This document describes the process that personnel in the primary (AA) review divisions in the Office of New Animal Drug Evaluation (ONADE) use to respond to requests for food-use authorizations.[1]

The process includes:

- Defining food-use authorization;
- Assessing the submission and routing the request for food-use authorization through CVM;

[1] "Primary (AA) review divisions" refers to the Generic Animal Drugs Team, the Division of Production Drugs, and the Division of Therapeutic Drugs for Food Animals. The specific personnel responsible for the submission are designated by staff-level procedures and are not assigned in this document.

- Procedure if the food-use authorization request includes an A-0000 submission;
- Action when the consulting review returns to you;
- Content of food-use authorization letters granting original (O submissions) or amended (D submissions) food-use authorizations;
- Content of a letter denying a food-use authorization request;
- Preparing an acknowledgement letter to transmit additional comments that cannot be communicated in the food-use authorization letter, when applicable; and
- Procedure when CVM rescinds a food-use authorization.

It DOES NOT explain the information the Division of Human Food Safety (DHFS) evaluates when responding to a request for a food-use authorization, or the format and content of the food-use authorization table. For this information see P&P 1243.4041.

II. WHAT IS A FOOD-USE AUTHORIZATION?

A food-use authorization permits the use of edible tissues from terrestrial and aquatic animal species treated with investigational new animal drugs for food use after FDA has evaluated any potential public health hazards.[2] The food-use authorization recommends appropriate mitigations of those hazards to ensure the safety of the edible products (e.g., tissues, milk, eggs, and honey) entering the human or animal food chain.

Sponsors of investigational files (INADs or JINADs) may request permission to use clinical investigational animals or their edible products as human or animal food.[3] ONADE may grant these requests after an appropriate review under the provisions of 21 CFR 511.1(b). Sponsors must wait until they receive written concurrence from the Director, ONADE (i.e., via a food-use authorization letter), before they use investigational animals for human or animal food purposes (21 CFR 511.1(b)(4)(v)(a)).

[2] In some case, the food-use authorization may also include animals treated with the vehicle (i.e., excipient components of the formulation). The DHFS includes the appropriate information in the authorization table if vehicle-treated animals are included in the authorization.
[3] Throughout this document, (J)INAD(s) is used and is intended to include INAD(s) and JINAD(s).

CVM encourages drug sponsors to request an appropriate number of animals, commensurate with their anticipated field trials, when requesting the original food-use authorization. In some instances, however, the sponsor may need to amend an original authorization to provide for additional animals or to refine the treatment regimen (i.e., changes in route of administration, drug formulation, dose, dosing frequency, claim, or class of animals to be treated). Additionally, if the original authorization is limited by the amount of food safety information available at the time of the request, we may require the sponsor to submit an amended authorization request to provide information that may shorten the investigation preslaughter withdrawal or milk discard period assignments.

We code food-use authorizations as O (original) or D (amended) in the Submission Tracking and Reporting System (STARS).

III. INITIAL ASSESSMENT OF THE SUBMISSION

A. Read the entire cover letter to determine the purpose(s) of the submission and what information is included.

B. If the food-use authorization request is included with an A-0000 submission, follow the instructions provided in Section IV below to create a separate O submission to address only the authorization request.[4]

C. Determine if the sponsor has submitted either a claim for a categorical exclusion or an environmental assessment (X submission) for the (J)INAD. If neither one is found in STARS, contact the sponsor and remind them that under 21 CFR 511.1(b)(10) they must submit one of these in order to maintain an investigational exemption.

D. Conduct an initial assessment of the O or D submission and determine whether the information is sufficiently complete for review. In general, the minimum information necessary for a food-use authorization review follows:

1. Composition of the experimental drug product, including at least the chemical names and proportions of the active ingredient(s) and all excipient(s);

2. Dosage form;

[4] See P&P 1240.3000 and 1240.3010 for further information on the initial (A-0000) submission for an (J)INAD.

3. Dose(s) and route(s) of administration;

4. Frequency and duration of dosing;

5. Target animal species;

6. Number(s) of animals requested

Review the information in items 1 through 6 above consistent with the AA reviewer's understanding of the project(s) proposed under the (J)INAD. Verify the appropriate number of animals requested for the studies needed to complete the requirements for approval. If the sponsor requests a number of animals that seems excessive, or if the requested number would raise public health concerns based on the information provided, we may grant fewer animals than the sponsor requested.

If the food use authorization request does not contain the information listed in 1 through 6 above, or if you believe that the request is deficient for another reason, discuss the submission with the DHFS. If you and the DHFS agree that the food use authorization request is not sufficiently complete for review, issue a letter refusing to review the submission.[5]

E. Confirm that a categorical exclusion has been granted for the (J)INAD, or if a previously provided Environmental Assessment (EA) or Finding of No Significant Impact (FONSI) is still valid for the (J)INAD.[6]

F. If the information is sufficiently complete for review, request a consulting review from the DHFS.[7] Send one copy of the entire submission. The DHFS determines which team has the "lead" and requests second level consults as needed. The DHFS reviewer reviews the information in the submission and determines whether to grant a food-use authorization.[8] If it is not clear whether you or the DHFS reviewer should review specific information (for example, injection site observation data) included in the submission, communicate with the DHFS consulting reviewer early in the review timeframe.

[5] See P&P 1243.2050 for further information on refusing to review a submission.
[6] See P&P 1243.7220 for further information on environmental review considerations.
[7] See P&P 1243.3200 for information on routing a request for a consulting review through STARS.
[8] See P&P 1243.4041 for a description of the type of information the DHFS will review for a food-use authorization.

Note: Food-use authorization requests that ONLY ask for additional animals do not typically require review by DHFS. Food-use authorization requests that ONLY ask for waiver of notification of slaughter do not typically require review by the DHFS. Contact the DHFS to determine if a consulting review request is appropriate.

G. The AA reviewer or the DFHS reviewer may request an amendment if they need information to complete the review.[9] When possible, coordinate amendment requests to minimize the number of amendments needed.

IV. WHAT TO DO IF THE REQUEST IS INCLUDED WITH AN A-0000 SUBMISSION

Sometimes sponsors include the food-use authorization request as part of an A-0000 submission. In this case, separate the authorization request by having the triplicate copy of the submission recoded as an O submission in STARS so that you (or other reviewers, if appropriate) can review it separately.

Before you send the recoded O submission to the DHFS, make a note on the routing form directing them to the appropriate section(s) of the submission.

The AA review and subsequent letter should document that the submission was split and that only the authorization-related information is reviewed in the O submission.

V. PREPARING THE AA REVIEW DOCUMENT

Based on the information provided in the submission, the DHFS recommends one of the following actions:

Grant authorization - The request for a food-use authorization is appropriate and conditions for the safe use of the investigational new animal drug in the requested target animal species provided;

OR

Deny authorization – Deny the request for the food-use authorization until the sponsor provides requested information that ONADE determines acceptable.

[9] See P&P 1243.3026 for further information on requesting amendments.

Prepare a review document using the Office template and the instructions provided in P&P 1243.3009.

The AA review document should:

A. Indicate the type of letter(s) to issue.[10]

B. Describe any minor changes that the AA reviewer made to the authorization table provided by the DHFS (normally transmit the authorization conditions as provided). If you need changes, contact the DHFS reviewer and discuss what changes to make. Summarize these discussions and the agreed upon changes to the authorization table in the AA reviewer's "Submission Summary."

C. Document that you split the A-0000 submission and that we reviewed only the authorization-related information in the O submission, if applicable.

D. Summarize the status of previous authorizations granted under the (J)INAD, if the submission is an amended authorization request.

Amended authorizations may replace (supersede) previous authorizations, or granted in addition to previous authorizations. For example, a replacement authorization is appropriate if only the number of animals changes, and all other conditions of a previous authorization remain the same. In some cases, we may need to supersede previous authorizations. We would do this when the administrative record is not clear about the conditions of the authorization. Concurrent authorizations are appropriate when one or more of the conditions change, such as adding a new class of a species, changing the dose, and/or adding a new variation within a major route of administration (i.e., IM vs. SC injection).

The AA review and letter should clearly indicate the status of each previous authorization granted. For each authorization, note whether still valid, or whether superseded by a subsequent authorization.

When determining the total number of animals granted for an amended authorization, consider the following examples.

[10] See P&P 1243.3033 for a list of permissible final actions for food use authorizations.

Example 1:

In the original authorization, the sponsor requests authorization for 200 lactating dairy cattle treated with up to 10 mg/kg (drugimycin) once by subcutaneous (SC) injection. The current submission is a request for 1,000 additional animals treated under the same conditions. The total number now authorized for these conditions is 1,200 (the total granted in the original authorization plus the current request). The actual number of animals remaining is 1,200 minus any animals already used.

The AA reviewer may (but is not required to) indicate in the review how many animals remain, based on other submissions provided by the sponsor, such as drug shipment notices, animal disposition notices, or animal disposition records provided in a data submission.

Example 2:

We previously granted the sponsor authorization for 1,200 lactating dairy cattle treated with drugimycin at up to 10 mg/kg once by SC injection. The current submission requests 600 lactating dairy cattle treated with drugimycin at up to 10 mg/kg once by intramuscular (IM) injection. This variation within the same route of administration and concurrent authorizations is appropriate. In other words, ONADE authorizes the sponsor now to treat 1,200 lactating dairy cattle treated under the conditions previously authorized (the actual number remaining is 1,200 minus those animals already used) AND 600 lactating dairy cattle treated under the new conditions (IM injection). In this case, do not add together the number of animals, because the authorizations differ in regard to the treatment conditions (for this example, route of administration).

Example 3:

Amended authorizations for aquaculture drugs generally supersede the previous authorization. With each amended authorization, the total number of animals authorized starts over at zero as of the date the sponsor receives the letter.

A table created in the AA review summarizes the status of previous authorizations, as the following example shows:

Submission Identification	Date of Authorization Letter	Summary of Authorization Terms	Status
I-123456 O-0001	January 11, 2007	200 lactating dairy cattle treated with drugimycin at up to 10 mg/kg once by SC injection; 24-hour milk discard and 5-day slaughter withdrawal assigned; waiver of notification of slaughter granted.	superseded by D-0011
I-123456 D-0011	May 17, 2007	request for 1,000 additional animals (new total of 1,200) treated as described in O-0001	currently valid
I-123456 D-0019		600 lactating dairy cattle treated with drugimycin up to 10 mg/kg once by IM injection (new route); 24-hour milk discard and 5-day slaughter withdrawal assigned; waiver of notification of slaughter granted.	current submission; currently valid

E. Address any other requests made by the sponsor in the submission. Examples include, but are not limited to:

1. a request for a categorical exclusion for the (J)INAD

If the current submission contains a request for categorical exclusion or an environmental assessment, see P&P 1243.7220 for instructions on creating a separate submission to evaluate these requests.

2. inclusion of investigational labeling

If the sponsor includes investigational labeling (or labeling language) in the submission, state whether it is acceptable (i.e., does the investigational caution statement match the statement provided in 21 CFR 511.1?).

If the sponsor does not submit investigational labeling to the (J)INAD file, note that in the AA review and use the boilerplate language provided in the template for the letter.

3. request for a waiver from the notification of slaughter

If the sponsor requests, CVM may waive the requirement for notification (21 CFR 511.1(b)(5)(iii)) of the date and place of slaughter, if the sponsor states that treated animals will remain under investigational conditions and under their supervision for the established drug withdrawal period. Use the boilerplate language provided in the template for the letter.

F. Provide any additional comments from the AA review to transmit in the letter(s). These comments vary depending on the type of information submitted, and/or as directed by staff-level procedures.

VI. PREPARING AN ORIGINAL FOOD-USE AUTHORIZATION LETTER

An original food-use authorization is coded in STARS as an O submission. Use the original authorization letter template provided by the office. The Office Director is the signature authority for food use authorization letters.

In addition to the authorization table, the original authorization letter includes:

A. boilerplate language regarding the Notice of Claimed Investigational Exemption (NCIE) forms, rendering, and other important information from the regulations. Do not change or delete these paragraphs.

B. for products used in terrestrial species, a paragraph regarding the requirement for notification to CVM and USDA of the date and place of slaughter. Choose the correct notification paragraph based on the information submitted.

C. additional boilerplate paragraphs regarding investigational labeling, if needed.

D. an “Additional Comments” section. Include the boilerplate comments and add any other comments specified by team or division-level procedures.

VII. PREPARING AN AMENDED FOOD-USE AUTHORIZATION LETTER

An amended food-use authorization is coded in STARS as a D submission. Use the amended authorization letter template provided by the office. The Office Director is the signature authority for amended food use authorization letters.

In addition to the authorization table, the amended authorization letter includes:

A. language clarifying the status of previous authorization(s). Use the appropriate paragraph(s).

B. boilerplate language regarding the Notice of Claimed Investigational Exemption (NCIE) forms, rendering, and other important information from the regulations. Do not change or delete these paragraphs.

C. for products used in terrestrial species, a paragraph regarding the requirement for notification to CVM and USDA of the date and place of slaughter. Choose the correct notification paragraph based on the information submitted.

D. additional boilerplate paragraphs regarding investigational labeling, if needed.

E. an "Additional Comments" section. Include the boilerplate comments and add any other comments specified by team or division-level procedures.

VIII. PREPARING A LETTER FOR A FOOD-USE AUTHORIZATION THAT IS DENIED

In some instances CVM is unable to grant a food-use authorization. In these cases, we prepare a food-use authorization denied letter. Generally, we ask for additional information in the letter. When the sponsor provides information we find acceptable, we may grant the food-use authorization.

For example, we will deny a food-use authorization:

- if the DHFS determines it does not have enough information to grant the authorization.

- if the sponsor is not granted categorical exclusion of the (J)INAD from the requirement to prepare an EA or provided an acceptable EA.

- in the rare case where a previously prepared EA or Finding of No Significant Impact (FONSI) is no longer valid.

In these cases, prepare an authorization denied letter declining the food-use authorization request. Appendix 1 contains a sample authorization denied letter. The Office Director is the signature authority for authorization denied letters.

IX. PREPARING A SEPARATE ACK LETTER TO TRANSMIT ADDITIONAL COMMENTS

Include office boilerplate regarding notification of slaughter, drug shipment notices, and other general information related to the food use authorization in the authorization letter. However, prepare a separate acknowledgement letter to convey comments to the sponsor that do not relate directly to the food-use authorization and/or cannot be shared with USDA/FSIS (e.g., if the information is proprietary).

If you send separate letters (ACK and AUTH) , add a sentence to the first paragraph of each of the letters indicating a separate letter transmits additional comments.

Follow the format for letters provided in P&P 1243.3010. The division director (or GADT leader) is the signature authority for the acknowledgement letter. Include both letters (acknowledgement and authorization) in the final action package, and choose ACK/AUTH as the final action code on the final action form.

X. ASSEMBLING AND ROUTING THE FINAL ACTION PACKAGE

A. Assembling the final action package

Follow the procedures described in P&P 1243.3005 and P&P 1243.3030 to prepare clean electronic documents and assemble the final action package.

The final action package includes:

1. Final copies of the AA reviewer's and consulting reviewer's reviews.

2. The original letter(s) to the sponsor and an envelope addressed to the sponsor. If you prepare ACK and AUTH letters, include two envelopes. If

authorization is granted, include a cc: block with "USDA/FSIS" indicated below the enclosure line.[11]

NOTE: Do not provide USDA/FSIS with copies of aquaculture authorization letters.

3. A photocopy of the unsigned authorization letter for USDA/FSIS: Write "USDA/FSIS" in pencil in the upper right-hand corner on the first page of their copy of the letter. Check or circle the cc: for USDA/FSIS on the USDA/FSIS copy of the letter. Flag the signature block for the person who signs all copies of the letter. The DCU date-stamps the photocopy of the letter with the same date as the original letter. Also include an envelope addressed to USDA/FSIS.

4. The official file (pink) copy of the letter. Use the following cc: block on the pink copy only (except aquaculture authorization letters):

cc: Document Control Unit, for the administrative file of:
X-XXXXXX-X-XXXX-OT
USDA/FSIS

Include the concurrence table provided in the template on the pink copy only.

B. Routing the final action package

Complete the final approval package routing section of the final action form as follows:

HFV-# for team
HFV-# for division [as per division SOPs]
HFV-190
HFV-107
HFV-100 [Director, ONADE has signature authority]
HFV-190
HFV-199

[11] USDA/FSIS should also be included in the cc: block in letters granting only a waiver of notification of slaughter (for example, an amended authorization in which the sponsor did not request a waiver in the original authorization request).

C. Place the electronic documents on the S:drive for review by the Quality Assurance Team.

Send the paper document to the QA Team thorough the DCU. Prepare these as final, not draft, documents and QA Team reviews them electronically. If the QA Team finds errors, omissions, etc., the QA Team advises the AA reviewer, via email, and returns the package to the AA reviewer for correction of the paper copy. Do not route the package through the DCU again. The QA team tracks the package with an electronic tracking system.

D. Prepare and send the electronic files for archiving as described in 1243.3030.

The QA team sends an email notifying the review division that the Office Director has signed the package (usually on the day he signs it) and requesting that the reviewer send the electronic files for archiving.

XI. RESCINDING A FOOD-USE AUTHORIZATION

If, at some point after a food-use authorization is granted, CVM determines that investigational use is no longer consistent with the public health, CVM rescinds that food-use authorization. For example, this can occur when, after we grant the food-use authorization, data implicate an ingredient in an investigational formulation as a suspect carcinogen. In this case, we recind the food-use authorization until resolving public health issues associated with the suspect ingredient.

Use the following procedure to rescind a food-use authorization:[12]

A. The AA review division initiates a Q submission. Send a consulting review request to the DHFS. The DHFS prepares a review describing the circumstances that make it necessary to rescind the authorization. The "Transmit to Sponsor" section of the DHFS consulting review indicates why the authorization is being rescinded, and any "next steps" that the sponsor could take to reinstate the authorization.

[12] Use the office template for this letter.

B. The AA review division prepares a letter for the sponsor, and, for products used in terrestrial species, a separate letter notifying USDA/FSIS of the rescission. The Office Director signs both letters.

Appendix 2 contains a sample letter for when we are rescinding an authorization. Appendix 3 contains a sample letter notifying USDA/FSIS that we have rescinded an authorization.

C. The AA review division follows the procedures described in P&P 1243.3005 and P&P 1243.3030 to prepare clean electronic documents and assemble the final action package that includes:

1. Final copies of the AA reviewer's and consulting reviewer's reviews.

2. The original letter to the sponsor and an envelope addressed to the sponsor.

3. The original letter for USDA/FSIS. Flag the signature block for the person who signs all copies of the letter. The DCU date-stamps the photocopy of the letter with the same date as the original letter. Also include an envelope addressed to USDA/FSIS.

4. The official file (pink) copy of both letters.

D. The AA division completes the final approval package routing section of the final action form and routes the package as follows:

HFV-# for team
HFV-# for division [as per division SOPs]
HFV-190
HFV-107
HFV-100 [Director, ONADE has signature authority]
HFV-190
HFV-199

E. Place the electronic documents on the S:drive for review by the Quality Assurance Team.

F. Prepare and send the electronic files for archiving as described in 1243.3030.

XII. REFERENCES

Code of Federal Regulations (Title 21)

Part 511 New Animal Drugs for Investigational Use

CVM Program Policy and Procedure Manual

1240.3010 - Processing Original Investigational New Animal Drug Applications

1243.2050 - Refuse to File and Refuse to Review

1243.3005 - Creating Clean Electronic Documents

1243.3009 - Format and Style Conventions for Reviews and Submission Summaries

1243.3010 - Format and Style Conventions for Letters

1243.3026 - Amending Stars Submissions

1243.3030 - Completing Final Action Packages for STARS Submissions

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

1243.4041 - Investigational Food-Use Authorizations: The Role of the Division of Human Food Safety Reviewer

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

XIII. VERSION HISTORY

March 31, 2009 – Original version

APPENDIX 1 – SAMPLE LETTER FOR A DENIED AUTHORIZATION

I-XXXXXX-O-XXXX-OT

Drug Company International
Attention: John Doe, DVM, PhD
Manager, Regulatory Affairs
1100 Industrial Drive, Suite 500
Anytown, NJ 55555

Re: Request for food-use authorization for <*species (and class if applicable)*> treated with <*drug established name*>

Dear Dr. Doe:

We deny your request for an <*original or amended*> food-use authorization. In a letter dated <*date of cover letter accompanying submission*>, you requested food-use authorization for up to <*number*> <*species (and class if applicable)*> treated with up to <*maximum dosage*> of <*proprietary name*> <*(established name(s))*> <*dosage form if not part of the proprietary name*>. You also requested a <*number*> day pre-slaughter withdrawal period <*if applicable, insert* "and a <*number hour/day*> milk discard time">. < *If applicable, insert* "The reference product for this proposed generic product is <*name of reference product*> sponsored by <*company name*> under NADA XXX-XXX.">

We are denying your request at this time because:

<Insert the reason(s) for denial. Describe the specific concerns and do not use general terms like "inconsistent with the public health." Use a list or delete the "because" and/or the colon and continue the sentence.>

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact <*name, position, team or division or office name, and contact number*>.

Sincerely,

<office director's name and degrees>
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

cc: Document Control Unit, for the administrative file of:
I-XXXXXX-O-XXXX-OT

Insert or delete rows and columns and modify management titles in the concurrence table as necessary.

Concurrence	Signature & Date
<*individual name*>, Primary Reviewer, <*name of team*>	
<*individual name*>, Leader, <*name of team*>	
<*individual name*>, Director, <*insert name of Division*>	
<*individual name*>, Leader, Quality Assurance Team	

Other administrative information:
not applicable
<Not applicable is the standard information here. This area is for the preparer line and notation of electronic copies. If you document these things, delete "not applicable" in the field and add the information.>

APPENDIX 2 – SAMPLE LETTER FOR RESCIND NOTIFICATION FOR A SPONSOR

Note that this is a sample letter that notifies the company that we are rescinding a food use authorization that we previously granted.

I-XXXXXX-Q-XXXX-OT

Drug Company International
Attention: John Doe, DVM, PhD
Manager, Regulatory Affairs
1100 Industrial Drive, Suite 500
Anytown, NJ 55555

Re: Rescind investigational food-use authorization for <*drug established name*>

Dear Dr. Doe:

We recently became aware of new information regarding the human food safety of <*drug established name*>, the active ingredient in <*proprietary name and dosage form if not part of the proprietary name*>. The specific information that raises new human food safety concerns is <*describe the basis of the decision to rescind food-use authorization*>.

Effective immediately, we hereby deny your investigational food-use authorization for the use of <*drug established name*> under this (J)INAD. This denial supersedes our authorization letter dated January 1, 1901 (X-XXXX). Our decision to deny your food-use authorization is based on the information described above and our desire to limit the public's exposure to a public health hazard. Please communicate this decision to your (J)INAD investigators immediately. <*For drugs used in terrestrial species, add the following sentence:* "We will notify USDA/FSIS of this decision."*>*

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact <*name, position, team or division or office name, and contact number*>.

Sincerely,

<office director's name and degrees>
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

cc: Document Control Unit, for the administrative file of:
I-XXXXXX-O-XXXX-OT

Insert or delete rows and columns and modify management titles in the concurrence table as necessary.

Concurrence	Signature & Date
<*individual name*>, Primary Reviewer, <*name of team*>	
<*individual name*>, Leader, <*name of team*>	
<*individual name*>, Director, <*insert name of Division*>	
<*individual name*>, Leader, Quality Assurance Team	

Other administrative information:
not applicable
<Not applicable is the standard information here. This area is for the preparer line and notation of electronic copies. If you document these things, delete "not applicable" in the field and add the information.>

APPENDIX 3 – SAMPLE LETTER FOR RESCIND NOTIFICATION FOR USDA/FSIS

Note that this is a sample letter that notifies USDA/FSIS that we are rescinding a food use authorization that we previously granted.

I-XXXXXX-Q-XXXX-OT

Residue Staff
USDA/FSIS
Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

Re: Rescind of investigational food-use authorization for <*drug established name*>

Dear Sir or Madam:

We recently became aware of new information regarding the human food safety of <*drug established name*>, the active ingredient in <*proprietary name and dosage form if not part of the proprietary name*>. <*Company name*> is investigating the use of this product in food-producing animals under the investigational new animal drug ((J)INAD) file I-XXXXXX. As a result of our findings, effective immediately, we are denying the investigational food-use authorization for the use of <*drug established name*> under this (J)INAD orignally granted in an authorization letter dated <*date*>. We are notifying <*company name*> of our decision in a separate letter.

If you have any questions relating to this letter, please contact <*name, position, team or division or office name, and contact number*>.

Sincerely,

<*office director's name and degrees*>
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

cc: Document Control Unit, for the administrative file of:
I-XXXXXX-O-XXXX-OT

Insert or delete rows and columns and modify management titles in the concurrence table as necessary.

Concurrence	Signature & Date
<*individual name*>, Primary Reviewer, <*name of team*>	
<*individual name*>, Leader, <*name of team*>	
<*individual name*>, Director, <*insert name of Division*>	
<*individual name*>, Leader, Quality Assurance Team	

Other administrative information:
not applicable
<Not applicable is the standard information here. This area is for the preparer line and notation of electronic copies. If you document these things, delete "not applicable" in the field and add the information.>