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Guidance for Industry

How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format to CVM

(THIS VERSION OF THE GUIDANCE REPLACES THE VERSION DATED JUNE 2007)

This guidance document is intended to provide instructions on how to submit Notices of Final Disposition of Animals (NFDAs) in electronic format to the Center for Veterinary Medicine (CVM or the Center). The guidance was revised to update the phone number for the Electronic Document Control Unit and to replace the web site to submit electronic comments.

Comments and suggestions regarding this document should be sent to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the exact title of the document. Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

For questions regarding this document, contact Margaret Zabriski, Center for Veterinary Medicine (HFV-010), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9143, E-mail: margaret.zabriski@fda.hhs.gov.

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. The valid OMB control number for this information collection is 0910-0453. The time required to complete this information collection is estimated to vary from 15 minutes to 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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GUIDANCE FOR INDUSTRY[1]

HOW TO SUBMIT A NOTICE OF FINAL DISPOSITION OF INVESTIGATIONAL ANIMALS NOT INTENDED FOR IMMEDIATE SLAUGHTER IN ELECTRONIC FORMAT TO CVM

This guidance represents the Agency's current thinking on how to submit a Notice of Final Disposition of Investigational Animals not intended for immediate slaughter in electronic format to CVM. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statue and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides advice to industry regarding the procedures to submit a Notice of Final Disposition of Investigational Animals (NFDA) in electronic format to the Center for Veterinary Medicine (CVM)

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

CVM monitors the final disposition of animals used to investigate new animal drugs. Monitoring of the final disposition of investigational animals is consistent with CVM's responsibility to protect the public health under the Federal Food, Drug, and Cosmetic Act. Disposition refers to the fate of the animals at the conclusion of the study. Examples of animal disposition include slaughtered for food, slaughtered for rendering, returned to the herd, incinerated, or returned to the owner. This information allows CVM to make sure that edible products derived from investigational food producing animals are not used for food unless authorization has been granted. CVM issues a slaughter authorization to new animal drug applicants (applicants) which contains the terms under which edible products from such animals

[1] This guidance has been prepared by CVM. For additional copies, access the document on the Internet at the CVM Home Page (http://www.fda.gov/cvm/default.html), or send a request to the Communications Staff, HFV-12, 7519 Standish Place, Rockville, MD 20855.

may be used for food (21 CFR 511.1(b)(5)). Authorization letters, issued by CVM, request that applicants submit NFDAs for investigational animals. This guidance gives applicants procedures to submit NFDAs.

The electronic submission of NFDAs is part of the Center's ongoing initiative to provide a method for paperless submissions.

To submit NFDAs electronically, the sponsor should use the NFDA form provided by CVM (FORM FDA 3487[2] OMB No. 0910-0453). The sponsor should enter the data directly into an Adobe® Acrobat® form and submit the form to CVM as an Adobe® PDF file (compatible with Adobe®Acrobat® 6.0)[3].

This guidance implements provisions of the Government Paperwork Elimination Act, Pub. L. No. 105-277, 112 Stat. 2681 (1998), which requires that executive agencies, by October 21, 2003, provide: (1) for the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures when practicable.

An NFDA should be submitted electronically from the applicants to CVM. For reasons of security and verifying the sender's identity, the applicant should register each individual participant, including a coordinator, and all individuals that will be submitting electronic submissions, with the Center as outlined in Guidance for Industry #108 "How to Submit Information in Electronic Format to CVM using the FDA Electronic Submission Gateway" available at the Center's Guidance Page (http://www.fda.gov/cvm/guidance/published.htm).

Electronic records may be submitted instead of paper records provided the requirements of 21 CFR 11.2 are met. The procedures in this guidance are designed to provide for a means of electronic submission that meet the requirements of Part 11. If an applicant does not follow this guidance to submit an NFDA electronically, the applicant should consult with CVM regarding alternative methods for electronic submission that meet the requirements of Part 11 or submit the NFDAs in paper.

II. NOTICE OF FINAL ANIMAL DISPOSITION FORM

A copy of the FORM FDA 3487 Notice of Final Disposition of Animals Not Intended for Immediate Slaughter (for use with electronic submissions) is available on the CVM Electronic Submission Page at http://www.fda.gov/cvm/esubstoc.html.

[2] A copy of the form along with instructions for completing it can be found on the CVM Electronic Submissions Project Page, http://www.fda.gov/cvm/esubstoc.html.
[3] FDA use of specific products does not constitute an endorsement of those products.

III. CHECKLIST FOR ELECTRONIC SUBMISSION OF NFDAS USING FORM FDA 3487

1. Open the Final Disposition FORM FDA 3487.
2. Fill in all of the applicable fields of the NFDA.
3. Select the "*Insert Comments*" button to add a PDF file containing any comments regarding the NFDA, if necessary.
4. Once the form is completed, select the "*Validate*" button to verify all of the required fields are completed. Those fields that are required will be highlighted and must be completed before the form can be sent to CVM.
5. Select the "*Save*" button to save all information on the form.
6. Select the "*Signature*" button to digitally sign the form. Once the form is digitally signed, you cannot make any changes because all of the fields will be locked for editing.
7. Follow the steps outlined in **Guidance for Industry #108, Section IV.J – Sending a Submission to FDA CVM using the FDA ESG** to submit your form to CVM.
8. If you do not receive a receipt from CVM by the third business day after you have sent the submission, call the Electronic Document Control Unit at 240-276-8584 to report the problem and find out what happened to your submission.