

Guidance for Industry

How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

Draft Guidance For Comment Purposes Only

This draft guidance describes how to use e-mail to submit a Notice of Final Disposition of Animals (NFDA) to the Center for Veterinary Medicine (CVM or the Center).

This draft guidance represents the Center's current thinking about using e-mail to submit an NFDA. It does not create or confer any rights for or on any person and does not bind the Food and Drug Administration (FDA) or the public.

E-mail submissions that follow this draft guidance will be compatible with CVM's current information technology capabilities. This will help ensure the confidentiality, integrity, security, and authenticity of data submitted to the Center. If a regulated company or person wishes to use an electronic approach other than that set forth in this draft guidance document, the Center will, on request, discuss alternative methods of submitting NFDAs.

Comments and suggestions regarding this document should be sent to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fisher's Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 00D-1313.

For questions regarding this draft document, contact Janis R. Messenheimer, Center for Veterinary Medicine, (HFV-135), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-7578, E-mail: jmessenh@cvm.fda.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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GUIDANCE FOR INDUSTRY¹

HOW TO USE E-MAIL TO SUBMIT AN NFDA

I. BACKGROUND

CVM monitors the final disposition of food animals treated with investigational new animal drugs in situations where the treated animals do not enter the human food chain immediately at the completion of the investigational study. Monitoring of the final disposition of such food animals is consistent with its responsibility to protect the public health under the Federal Food, Drug, and Cosmetic Act. In addition, acceptable standards of study conduct such as those set out in 21 CFR 514.117 would include sponsors accounting for the disposition of all animals treated with investigational new animal drugs (INADs). Furthermore, CVM requests this information because some animals are held for 30 days after the investigational drug withdrawal period ends and CVM does not request a notice of intent to slaughter for human food purposes for these animals. Animals held for this period may still be sent for slaughter, however. CVM issues a slaughter authorization letter to new animal drug sponsors (sponsors) which sets the terms under which animals treated with investigational new animal drugs may be slaughtered. 21 CFR 511(b)(5). Also in this letter, CVM requests that sponsors submit NFDAs for animals that are treated with investigational new animal drugs and are not intended for immediate slaughter. Currently, CVM receives NFDAs on paper. This draft guidance will give sponsors the option to submit an NFDA as an e-mail attachment by the Internet.

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

This draft 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.

This draft guidance document contains specific instructions for submitting NFDAs. Draft guidance #108, How to Use E-Mail to Submit Information to CVM, contains general instructions and specifications on submitting information electronically to

¹ This guidance and form have been prepared by CVM at FDA. For additional copies of this draft guidance and form, access the document on the Internet by connecting to the CVM Home Page at <http://www.fda.gov/cvm>, or send a request to the Communications Staff, HFV-12, 7500 Standish Place, Rockville, MD 20855.

CVM by e-mail. It is available on the CVM Home Page. When draft guidance #108 becomes final, sponsors should first register and follow the instructions in that guidance before submitting NFDAs as an e-mail attachment.

II. CHECKLIST FOR SUBMITTING AN NFDA USING ADOBE®ACROBAT® 4.0²

A sponsor submitting an electronic NFDA should send the NFDA as a single Portable Document Format (PDF) file attached to an e-mail. This checklist describes the process sponsors should follow to create a PDF file using a word processing program, print it to the Acrobat® Distiller, and submit the information. The PDF file can be created by other software.

1. Use a word processing software package to create a document following the form and containing the information requested in Section III.
2. Make sure Acrobat® Distiller is selected as the default printer.
3. Fill in all pertinent sections of FDA Form #3487, the NFDA form.
4. Print the word processing document to Acrobat® Distiller to create a PDF file.
5. Name the PDF file using an 8.3 file naming convention. Save the PDF file in the appropriate directory location and close the file.
6. Open the PDF file in Adobe® Acrobat® 4.0, select "Save As" and select the "Security" options for "Specify Password To: Open the Document". Enter your password and click OK. Verify the password by entering it again and then "Save" the PDF file.
7. Open your e-mail program and begin a new message.
8. Address it to **cvmdcu@cvm.fda.gov**.
9. Type the eleven character word **DISPOSITION** in the subject line, using all capital letters. Do not include any other punctuation or information in the subject line.
10. Do not type anything in the body of the message.
11. Attach the PDF file of the NFDA to the e-mail message.
12. Send the e-mail message.
13. If you have not received an acknowledgment receipt from CVM (stars@cvm.fda.gov) within three working days after you have sent the submission, call the Electronic Document Control Unit at 301-827-8277 to report the problem and find out what happened to your submission.

² This checklist uses Adobe Acrobat 4.0 for the purpose of example. FDA use of specific products does not constitute endorsement of those products. Sponsors can use other software to create files.

III. NOTICE OF FINAL ANIMAL DISPOSITION FORM

A copy of the FDA Form #3487 for electronic NFDA follows.

Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

Food and Drug Administration
Center for Veterinary Medicine (HFV-)
7500 Standish Place
Rockville, Maryland 20855
(E-mail:cvmdcu@cvm.fda.gov)

Date:
INAD No:
Study ID:
Notice No:

The sponsor, _____, submits a notice of final disposition of animals treated with investigational new animal drugs and not intended for immediate slaughter as requested by CVM authorization letter dated _____. This information is submitted in electronic form.

I. Animals Not Intended for Immediate Slaughter

1. Compound(s) used
Established name(s):
Trade name(s):
2. Species of animals:
3. Method of disposition:
4. Name and address of facility where animals were disposed:

5. Number of animals Treated:
6. Approximate date of disposition:
7. Comments:

Control:

II. Sponsor Information

1. Sponsor's name:
2. Sponsor's address:

3. Sponsor contact's name:
Telephone:
Fax:
E-mail address: