

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1313]

DMB

Display Date	6/26/02 10:02
Publication Date	6/29/02
Certifier	SN Reese

Draft Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#86) entitled "How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter" in the Center for Veterinary Medicine (CVM). This draft guidance is neither final nor is it in effect at this time. The draft guidance document is intended to provide guidance to new animal drug sponsors (sponsors) on how to submit a notice of final disposition of animals not intended for immediate slaughter (NFDA) as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This draft guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments on the draft guidance at any time, however, comments should be submitted by [*insert date 60 days after date of publication in the Federal Register*], to ensure their adequate consideration in preparation of the final document. Submit written comments on the information collection requirements by [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document.

Copies of the draft guidance document entitled "How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter" may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/>. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and electronic signatures final regulation. This regulation (21 CFR part 11) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This rule also established public docket number 92S-0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify in this public docket the types of documents that may be submitted in electronic form as those documents are identified in final guidance or regulations.

This docket is accessible on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/92s0251.92s0251.htm>.

The electronic submission of NFDA's is part of CVM's ongoing initiative to provide a method for paperless submissions. It reflects the principles behind the GPEA. The GPEA of 1998 (Public Law 105-277) requires Federal agencies, by October 21, 2003, to 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.

In order to submit NFDA's by e-mail, sponsors should first register and follow the instructions in draft guidance for industry (#108) entitled "How to Use E-Mail to Submit Information to the Center for Veterinary Medicine" when it becomes final.

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 (the act). In addition, acceptable standards of study conduct such as those set out in § 514.117 (21 CFR 514.117) would include sponsors accounting for the disposition of all animals treated with investigational new animal drugs. 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 investigational new animal drug sponsors that sets the terms under which animals treated with investigational new animal drugs may be slaughtered (§ 511.1(b)(5) (21 CFR 511.1(b)(5))). Also in this letter, CVM requests that sponsors submit NFDA's for animals that are treated with investigational new animal drugs and are not intended for immediate slaughter. NFDA's have historically been submitted to CVM on paper. This draft guidance will give sponsors the option to submit an NFDA as an e-mail attachment to CVM via the Internet.

II. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency'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 will not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Description: 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. CVM believes that monitoring of the final disposition of such food animals is consistent with its responsibility to protect the public health under the act. In addition, CVM believes that acceptable standards of study conduct such as those set out in § 514.117 would include sponsors accounting for the disposition of all animals treated with investigational new animal drugs. 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.

The draft guidance document describes the procedures for persons who are sponsors of new animal drugs who wish to file an NFDA electronically on FDA Form #3487. The information sponsors should include on the form includes the sponsor's name and address, and information about the treated animals. The likely respondents to this collection of information are new animal drug sponsors who have conducted clinical investigations under § 511.1(b).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3487	190	1.7	324	0.81	262

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

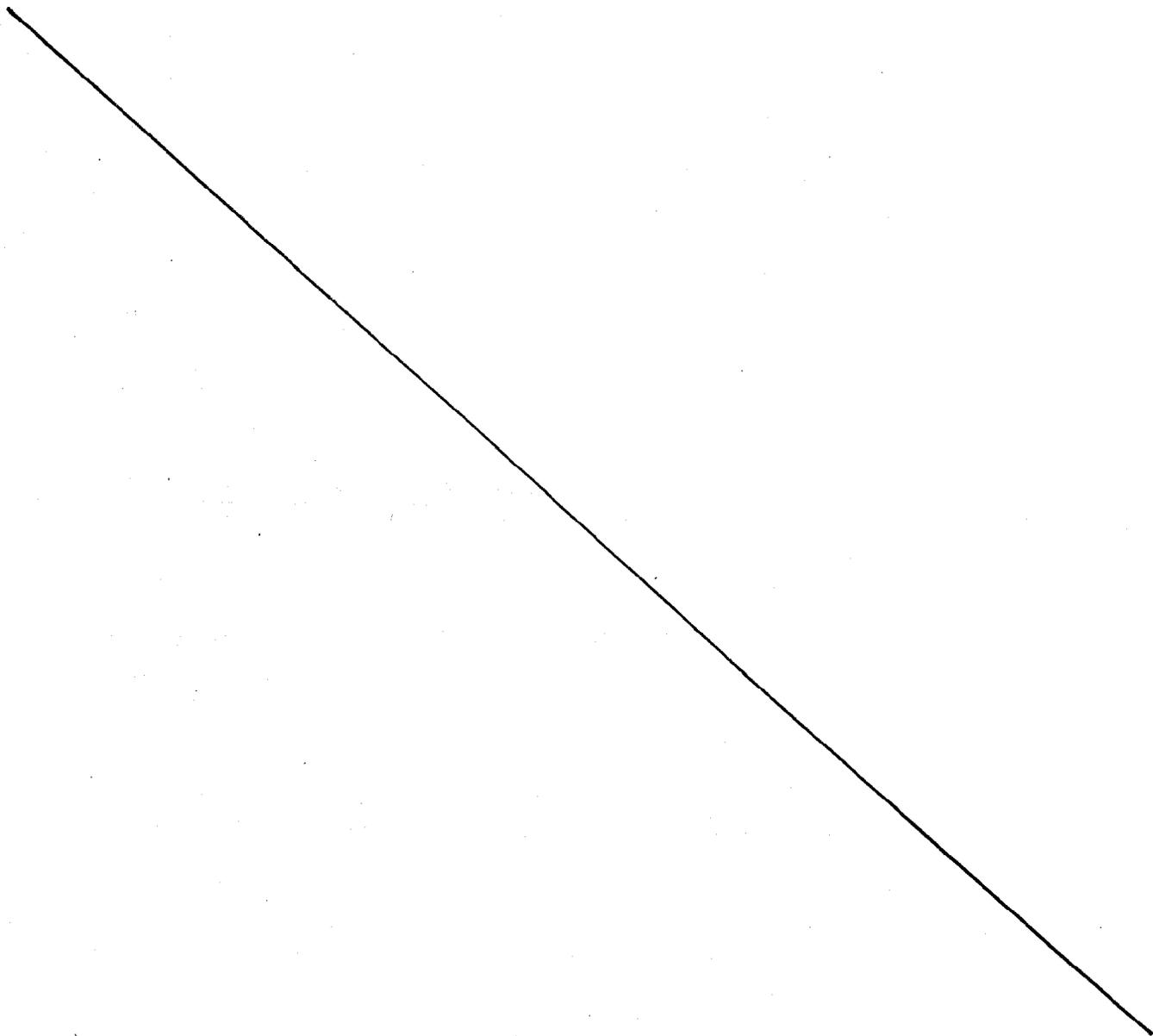
The estimates in Table 1 of this document resulted from discussions with new animal drug sponsors. The estimated burden includes NFDA's submitted on paper and by e-mail.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments by [*insert date 60 days after date of publication in the Federal Register*], to ensure

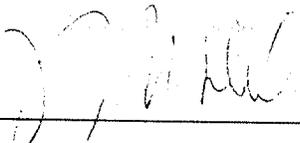
adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Submit written comments concerning the information collection requirements to the Dockets Management Branch by [*insert date 60 days after date of publication in the Federal Register*].



A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

