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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00D-1314]

**Draft Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#87) entitled "How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes" in the Center for Veterinary Medicine (CVM) and U.S. Department of Agriculture (USDA). This draft guidance is neither final nor is it in effect at this time. The purpose of this draft guidance document is to provide guidance to new animal drug sponsors (sponsors) on how to submit a notice of intent to slaughter for human food purposes (slaughter notices) as an e-mail attachment by Internet. This electronic submission is 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 This draft guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

**DATES:** Submit written comments on the draft guidance at any time, however, comments should be submitted by [*insert date 60 days after date of publication in the Federal Register*], to ensure their adequate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 collection of information 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**ADDRESSES:** Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. *NAL-1*

Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Copies of the draft guidance document entitled "How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes" may be obtained on the Internet from the CVM home page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 Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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](mailto:jmessenh@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; 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 that are identified in final guidances or regulations. This docket is accessible on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm>.

The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submissions. The draft guidance implements provisions of the GPEA. The GPEA of 1998 (Public Law 105-277) requires Federal agencies, by October 21, 2003, to provide for: (1) The option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) the use and acceptance of electronic signatures, when practicable. In order to submit slaughter notices by e-mail, sponsors should first register and follow the instructions in draft guidance for industry (#108) "How to Use E-Mail to Submit Information to the Center for Veterinary Medicine" when it becomes final.

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) gives FDA the authority to issue regulations setting out conditions for marketing animals treated with investigational new animal drugs for food use. Under this authority, FDA issued § 511.1(b)(4) (21 CFR 511.1(b)(4)) that requires that sponsor obtain authorization to slaughter these animals for food. Under § 511.1(b)(5), CVM issues a slaughter authorization letter to sponsors that sets the terms under which the animals treated with investigational new animal drugs may be slaughtered. USDA also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act (21 U.S.C. 601-95). To assist CVM and USDA with this monitoring, the slaughter authorization states that sponsors must submit slaughter notices each time such animals are to be slaughtered unless CVM waives the notice in the authorization letter. Currently, slaughter notices are submitted to CVM on paper. This guidance will give sponsors the option to submit a slaughter notice as an e-mail attachment to CVM and USDA by 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 a slaughter notice. 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 statute, 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 Intent to Slaughter for Human Food Purposes.

*Description:* Under § 511.1(b)(5), CVM issues slaughter authorizations for food animals treated with investigational new animal drugs. To assist CVM with the monitoring of the slaughter of food animals treated with investigational new animal drugs, the slaughter authorization letter CVM sends to sponsors states that they must submit slaughter notices each time such animals are to be slaughtered unless the authorization letter waives that notice. Currently, slaughter notices are

submitted to CVM on paper (OMB Control No. 0910-0117). This draft guidance will give sponsors the option to submit a slaughter notice as an e-mail attachment to CVM by the Internet.

The draft guidance describes the procedures for persons who are sponsors of new animal drugs and who wish to file a slaughter notice on FDA Form No. 3488 by e-mail. The information that should be filed on the form includes: Identify the sponsor, the animals to be slaughtered, and the compound used to treat the animals. The likely respondents to this collection of information are 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 BURDEN<sup>1</sup>

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3488	190	0.35	66	0.41	27

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

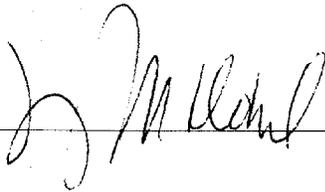
Submitting a slaughter notice electronically represents a new medium for submission of information currently submitted on paper. The reporting burden for compilation and submission of this information on paper is included in OMB clearance of the information collection provisions of § 511.1 (OMB Control No. 0910-0117). The estimates in table 1 of this document reflect the burden associated with putting the same information on FDA Form No. 3488 and resulted from discussions with sponsors about the time necessary to complete this form.

#### 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. 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 guidance. 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. Written comments concerning the information collection requirements must be received by [*insert date 60 days after date of publication in the*

**Federal Register**]. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/16/00  
June 16, 2000

  
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Margaret M. Dotzel  
Associate Commissioner for Policy

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COPY OF THE ORIGINAL**

Suzette N. Reese