

In the **Federal Register** of March 13, 2000 (65 FR 13405), the agency requested comments on the proposed collections of information. No comments were received.

Dated: June 22, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 13 and 14, 2000, 8:30 a.m. to 5 p.m.

Location: CDER Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jayne E. Peterson or Tony A. Slater, Jr., Center for Drug Evaluation and Research (CDER) (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 13, 2000, the committee will review five drug products for inclusion on a list of drug products that cannot be compounded because they have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see 21 CFR 216.24 (64 FR 10944, March 8, 1999)) whereby FDA amended its regulations to include such a list of drug products). In the **Federal Register** of January 4, 2000 (65 FR 256), FDA published a proposed rule amending these

regulations to add two drug products to the list: (1) Aminopyrine (all drug products containing aminopyrine) and (2) astemizole (all drug products containing astemizole). In addition to these two drug products, the committee will review the following three drug products: (1) Grepafloxacin (all drug products containing grepafloxacin), (2) troglitazone (all drug products containing troglitazone), and (3) cisapride (all drug products containing cisapride). Beginning at approximately 10 a.m., and continuing on July 14, 2000, at approximately 8:30 a.m., the committee will discuss and provide FDA with advice about drug products that present demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of those drug products.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the committee. Written submissions may be made to the contact person by July 3, 2000. On July 13, 2000, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. On July 14, 2000, oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the July 13 and 14, 2000, Pharmacy Compounding Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Pharmacy Compounding Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 20, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1313]

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 August 28, 2000 to ensure their adequate consideration in preparation of the final document. Submit written comments on the information collection requirements by August 28, 2000.

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 BURDEN ¹

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

¹ There 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 August 28, 2000, 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 August 28, 2000. 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: June 16, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-16392 Filed 6-26-00; 10:07 am]

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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.

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 August 28, 2000 to ensure their adequate consideration in preparation of the final document. Submit written comments on the collection of information requirements by August 28, 2000.

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 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

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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.

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I. Background

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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