collection of information to OMB for review and clearance.

Title: Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

Description: Under § 511.1(b) (21 CFR 511.1(b)), the Center for Veterinary Medicine (CVM) issues slaughter authorizations for food animals treated with investigational new animal drugs. To assist with monitoring the slaughter of food animals treated with investigational new animal drugs, a slaughter authorization letter is sent to sponsors by CVM which 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 guidance will give sponsors the option to submit a slaughter notice as an e-mail attachment to CVM by the Internet.

This final 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: Identification of the sponsor, the animals to be slaughtered, and the compound used to treat the animals.

Description of Respondents: The likely respondents for this collection of information are animal drug sponsors who have conducted clinical investigations under § 511.1(b). In the **Federal Register** of June 29, 2000 (65 FR 40106), FDA announced availability of this guidance as a draft document and requested public comment on the proposed collection of information. No comments were received on the estimated annual reporting burden. We therefore believe the annual reporting burden estimate of 27 hours should remain unchanged.

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
3488	190	0.35	66	0.41	27

[1] 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 estimates in table of this document resulted from discussions with sponsors about the time necessary to complete this form.

Dated: September 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1506]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 23, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 1025, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

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

Description: The Center for Veterinary Medicine (CVM), monitors 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 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 Federal Food, Drug, and Cosmetic Act. In addition, CVM believes that acceptable standards of study conduct, such as those set forth under 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. However, animals held for this period may still be sent for slaughter.

This guidance document describes the procedures for persons who are sponsors of new animal drugs who wish to file a notice of final disposition of animals (NFDA) not intended for immediate slaughter, electronically on FDA Form No. 3487. The information sponsors should include on the form includes the sponsor's name, address, and information about the treated animals.

Description of Respondents: The likely respondents for this collection of information are new animal drug sponsors who have conducted clinical investigations under 21 CFR 511.1(b).

In the **Federal Register** of June 29, 2000 (65 FR 40104), FDA announced the availability of this guidance as a draft document and requested public comment. In response to this notice, no comments were received on the annual reporting burden. We, therefore, believe the annual reporting burden of 262 hours should remain unchanged.

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 burden 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.

Dated: September 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–24266 Filed 9–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1316]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 23, 2000.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on How to Use E–Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation.

Description: As part of new animal drug development, sponsors often meet with the Center for Veterinary Medicine (CVM), scientists to formulate a rational approach for studies to be conducted, and to discuss how they meet the statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Requests for meetings and teleconferences about new animal drug submissions are currently submitted to CVM on paper. CVM is responsible for developing and administering a guidance that explains how to adhere to the Electronic Records; Electronic Signatures regulations (21 CFR part 11). These regulations provide for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy and complies with the Government Paperwork Elimination Act (GPEA). The GPEA requires Federal agencies, by October 21, 2003, to give persons who are required to maintain, submit, or disclose information, the option of doing so electronically, when practical, as a substitute for paper.

This guidance document describes the procedure for persons who are new animal drug sponsors who wish to submit a request for a meeting or teleconference to the Office of New Animal Drug Evaluation by e-mail on FDA Form No. 3489. The information sponsors should include on the form are: The sponsor's name and address, a list of requested participants, an indication of audiovisual needs, and an agenda.

Description of Respondents: The likely respondents for this collection of information are sponsors who will be conducting clinical investigations under 21 CFR 511.1(b). In the **Federal Register** of June 29, 2000 (65 FR 40108), the FDA announced the availability of this guidance as a draft document and requested public comment on the proposed collection of information. No comments were received on the estimated annual reporting burden. We therefore believe the annual reporting burden of 116 hours should remain unchanged.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,489	190	.88	168	0.69	116

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