

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1506]

OMB

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Certifier	<i>SNReese</i>

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 *[insert date 30 days after date of publication in the Federal Register]*.

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 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 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.

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