Dated: April 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9902 Filed 4–28–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0034]

Agency Information Collection Activities; Submission for Office and Management and Budget Review; Comment Request; Guidance for Industry on How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format to the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by June 1, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0453. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format to the Center for Veterinary Medicine—(OMB Control Number 0910–0453)—Extension

The Center for Veterinary Medicine (CVM) monitors the final disposition of investigational animals where such animals do not enter the human food chain immediately at the completion of an investigational study. CVM's monitoring of the final disposition of investigational food animals is intended to ensure that unsafe residues of new animal drugs do not get into the food supply. CVM issues a slaughter authorization letter to investigational new animal drug (INAD) sponsors that sets the terms under which investigational animals may be slaughtered (21 CFR 511.1(b)(5)). Also in the letter, CVM requests that sponsors submit a notice of final disposition of investigational animals (NFDA) not intended for immediate slaughter. NFDAs have historically been submitted to CVM on paper. CVM's guidance entitled "How to Submit a Notice of Final Disposition of Investigational Animals not Intended for Immediate Slaughter in Electronic Format to CVM" provides sponsors with an option to submit an NFDA as an e-mail attachment to CVM via the Internet.

The likely respondents are INAD sponsors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ Form No. 3487	Number of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
511.1(b)(5)	40	0.4	16	.08	1.3

[1] There are no capital or operating and maintenance costs associated with this collection of information.
[2] Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in table 1 of this document are the number of sponsors registered to make electronic submissions (40). The number of total annual responses is based on a review of the actual number of such submissions made between January 1, 2008, and December 31, 2008. Thus, FDA estimates the total reporting burden at 1.3 hours (16 x .08= 1.3 total hours).

Dated: April 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9901 Filed 4–28–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0055]

Agency Information Collection Activities; Submission for Office and Management and Budget Review; Comment Request; Guidance for Industry on How to Submit a Protocol Without Data in Electronic Format to the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by June 1, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0524. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information