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

Management, Food and Drug Administration, 1350 Piccard Dr., 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 Protocol Without Data in Electronic Format to the Center for Veterinary Medicine—(OMB Control Number 0910–0524)—Extension

Protocols for nonclinical laboratory studies (safety studies), are required under 21 CFR 58.120 for approval of new animal drugs. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Upon request by the animal drug sponsors, the Center for Veterinary Medicine (CVM) reviews protocols for safety and effectiveness studies for which CVM and the sponsor consider this to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application. The establishment of a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of new animal drug applications, is part of CVM's ongoing initiative to provide a method for paperless submissions. Sponsors may submit protocols to CVM in paper format. CVM's guidance on how to submit a study protocol permits sponsors to submit a protocol without data as an e-mail attachment via the Internet. Further, this guidance also electronically implements provisions of the Government Paperwork Elimination Act (GPEA). The GPEA required Federal agencies, by October 21, 2003, to provide the following: (1) The option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitution for paper and (2) the use and acceptance of electronic signatures, where applicable. FDA Form 3536 is used to facilitate the use of electronic submission of protocols. This collection of information is for the benefit of animal drug sponsors, giving them the flexibility to submit data for review via the Internet.

The likely respondents are sponsors of new animal drug applications.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ Form No. 3536	Number of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
514.117(b) & 58.120	40	1.8	72	20	14.4

[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 is 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, (72 x hours per response (.20) = 14.4 total hours)).

Dated: April 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10023 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–D–0153]

Draft Guidance for Industry and Food and Drug Administration Staff; Food and Drug Administration and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance for Industry and FDA Staff; FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act." This draft guidance is not final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, FDA is also publishing a notice of availability for a draft guidance entitled "Draft Guidance for Industry and FDA Staff; User Fees for 513(g) Requests for Information."

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on this draft guidance by July 28, 2010. Submit written or electronic comments on the collection of information by June 28, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written requests for single copies of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff; FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance and the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm., 1532, Silver Spring, MD 20993–0002, 301–796–6571, or Steve Ripley, Center for Biologics Evaluation and Research, (HFM–17),