

There are no Capital Costs, Operating costs, and/or Maintenance Costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Liz Elliott, NIGMS, NIH, Natcher Building, Room 2AN-18H, 45 Center Drive, MSC 6200, Bethesda, MD 20892-6200, or call non-toll-free number 301-594-2755 or e-mail your request, including your address to: [elliott@nigms.nih.gov](mailto:elliott@nigms.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: May 10, 2010.

**Sally Lee,**

*Executive Officer, National Institute of General Medical Sciences, National Institutes of Health.*

[FR Doc. 2010-11857 Filed 5-17-10; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0057]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway**

**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 17, 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: 202-395-6974, or e-mailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0454. 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., P150-400B, 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 Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway (OMB Control Number 0910-0454)—Extension**

The Center for Veterinary Medicine (CVM), accepts certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM's guidance entitled "Guidance for Industry: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway" outlines general standards to be used for the submission of any information by e-mail. The likely respondents are sponsors for new animal drug applications.

In the **Federal Register** of February 5, 2010 (75 FR 6038), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section/Form 3538	No. of Respondents	Annual Frequency per Response	Total Annual Responses <sup>2</sup>	Hours per Respondent	Total Hours
11.2	40	1.3	52	.08	4.2

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> 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 (52 x

hours per response (.08) = 4.2 total hours).

Dated: May 12, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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