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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 2006N-0432]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Use E-mail to Submit Information 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 *[insert date 30 days after date of publication in the Federal Register]*.

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.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (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 Information to the Center for Veterinary Medicine—21 CFR 11.2 (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 1992S-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 #108: How to Submit Information in Electronic Format by E-Mail" outlines general standards to be used for the submission of any information by e-mail.

In the **Federal Register** of November 8, 2006 (71 FR 65533), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

The likely respondents for this collection of information are sponsors for new animal drug applications.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses ²	Hours per Response	Total Hours
11.2	25	5.62	140	.08	11.2

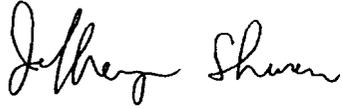
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Electronic submissions received between July 1, 2005, and June 30, 2006.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (25). The number of total annual responses is based on a review of the actual number of such

submissions made between July 1, 2005, and June 30, 2006. (140 x hours per response (.08) = 11.2 total hours.)

Dated: 2/7/07
February 7, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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