4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0519]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry # 108 on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration 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 [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: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0454 and title "Guidance for Industry # 108 on How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

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 # 108 on How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway--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 97S-0251 as required by § 11.2 (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 to CVM Using the FDA Electronic Submission Gateway" outlines general standards to be used for the submission of any information by email. The likely respondents are sponsors for new animal drug applications.

In the Federal Register of May 16, 2013 (78 FR 28851), 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[1]

21 CFR Part and Form FDA	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 11.2; Form FDA 3538	65	2.4	156	.08 (5 minutes)	13 (Rounded from 12.5)

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

Dated: August 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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