

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0173]

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Display Date 6-25-08
Publication Date 6-26-08
Certifier D. Hawkins

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Appeals of Science-Based Decisions Above the Division Level at 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, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0566. Also include the FDA docket number found in brackets in the heading of this document.

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.

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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.

Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine (OMB Control Number 0910-0566)—Extension

CVM's (Center for Veterinary Medicine) "Guidance for Industry #79—Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine" describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training or experience to be understood and resolved. Further, the guidance details information on how the agency intends to interpret and apply provisions of the existing regulations regarding internal agency review of decisions. In addition, the guidance outlines the established recommended procedures for persons who are applicants, including sponsor applicants or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When an applicant has a scientific disagreement and a written decision by CVM, the applicant may submit a request for review of that decision by following the established agency channels of supervision for review.

Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

In the **Federal Register** of March 26, 2008 (73 FR 16021), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.75	2	4	8	10	80

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

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents multiplied by the annual frequency of response equals the total annual responses. The number of hours per response is based on discussions with industry and may vary depending on the complexity of the issue(s) involved and the duration of the appeal process.

Dated: 6/19/08

June 19, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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Dawn P. Hawkins