



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0509]

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: 202-395-7285, or emailed to oir_submission@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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002 PRASStaff@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.

Appeals of Science-Based Decisions Above the Division Level at CVM--21 CFR 10.75 (OMB Control Number 0910-0566--Revision)

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

The Center for Veterinary Medicine's (CVM's) guidance for industry #79 entitled "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 procedures for persons who are sponsors, 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 a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

In the Federal Register of November 6, 2014 (79 FR 65976), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but it did not respond to any of the four collection of information topics solicited in the notice and therefore is not discussed in this document.

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

Table 1. – Estimated Annual Reporting Burden¹

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

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

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method, then CVM recommends that the applicant follow the procedure in guidance for industry #79. Of the two respondents who were advised on the procedure during the past 3 years, one has not followed up to initiate it and the other is working with the review team/group to resolve the issue(s). Therefore, this estimated annual reporting burden is based on CVM's previous experience in handling formal appeals for scientific disputes.

Dated: January 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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