4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by 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 oira_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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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.

Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine--21 CFR 10.75

OMB Control Number 0910-0566--Extension

The Center for Veterinary Medicine's (CVM's) Guidance for Industry (GIF) #79, "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine" (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052393.pdf), 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. The guidance details information on how CVM intends to apply provisions of existing regulations regarding internal review of Agency decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants, or manufacturers of 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 procedures discussed in the guidance.

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 procedures in GFI #79.

In the *Federal Register* of October 27, 2017 (82 FR 49836), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
10.75, Request for review of a scientific dispute	1	4	4	10	40

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

In the next 3 years, CVM anticipates receiving one or fewer requests for review of a scientific dispute per year, on average. We base our estimate on CVM's experience over the past 6 years in handling formal appeals for scientific disputes. The burden of this collection has changed. The number of respondents decreased from two to one annually, the number of responses per respondent remained at four annually, the hours per response remained at 10 annually, and the total number of hours decreased from 80 to 40. This decrease in the total hours is the result of a natural fluctuation in the number of respondents taking advantage of this dispute resolution process.

Dated: February 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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