



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-1652]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dispute Resolution Procedures for Science-Based Decisions on Products by the Center for Veterinary Medicine

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) 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:** Submit written comments (including recommendations) 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 submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 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, [PRASStaff@fda.hhs.gov](mailto: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.

Dispute Resolution Procedures for Science-Based Decisions on Products by the Center for

Veterinary Medicine--21 CFR 10.75

OMB Control Number 0910-0566--Extension

The Center for Veterinary Medicine (CVM) Guidance for Industry (GFI) #79, "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine" (<https://www.fda.gov/media/70279/download>), 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 who 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 found in GFI #79.

In the *Federal Register* of August 18, 2020 (85 FR 50827), 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<sup>1</sup>

21 CFR Part; Activity	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

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

We note that the 60-day notice included an inadvertent error in the estimated burden, which has been corrected in table 1. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: February 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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