

U.S. Food and Drug Administration
Dispute Resolution Procedures for Science-Based Decisions on Products
Regulated by the Center for Veterinary Medicine (CVM)

OMB Control No. 0910-0566

SUPPORTING STATEMENT Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations and accompanying guidance. Specifically, Congress enacted section 562 of the Federal Food, Drug, and Cosmetic Act (FFDCA or the act)(21 U.S.C. 360bbb-1), which directed the FDA to ensure that it had adequate dispute resolution procedures to provide for appropriate review of scientific controversies between the FDA and members of regulated industry, including possible review by a scientific advisory committee. To implement section 562, we amended 21 CFR 10.75 *Internal agency review of decisions*, the general appeal regulation applicable across all FDA components, to provide for advisory committee review (21 CFR 10.75(b)(2)). At the same time, we adopted an individual, center-based approach to the specific implementation of section 562's mandates, to be detailed in center-issued guidances (see 63 FR at 63979).

Accordingly, CVM has developed and issued *Guidance for Industry (GFI) #79, "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine"* available at:

<https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052393.pdf>. The guidance 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.

We therefore request extension of OMB approval for the information collection provisions found in the above referenced guidance and in 21 CFR Part 10.75 as applicable.

2. Purpose and Use of the Information Collection

Respondents to the collection of information include the private sector (for-profit) businesses including sponsors, applicants, or manufacturers who seek to resolve scientific controversy relating to a decision affecting animal drugs or other products that are regulated by CVM.

The information collection provides instruction to respondents that we believe will facilitate the resolution of such disputes and promote greater use of alternative dispute resolution techniques including informal neutral intervention, shuttle diplomacy, and mediation by the CVM Ombudsman.

3. Use of Improved Technology and Burden Reduction

The guidance does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in submitting their request for review. We believe 100% of respondents will use electronic means to satisfy the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. In accordance with section 562 of the FFDCA, FDA has established other center-specific collections relating to scientific dispute resolution including OMB Control Nos. 0910-0430, 0910-0563, and 0910-0738; however this collection of information exclusively supports scientific dispute resolution within CVM.

5. Impact on Small Businesses or Other Small Entities

The guidance provides information to assist a small business in preparing a request for review. We aid small businesses in complying with our requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We have provided a Small Business Guide on our website at <http://www.fda.gov/oc/industry/>.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. If not collected, the sponsor, applicant, or manufacturer would not be able to request review of a scientific controversy relating to a decision affecting their animal drugs or other products. CVM and the CVM Ombudsman would not be able to assess accurately the scientific controversy under dispute.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of October 27, 2017 (82 FR 49836). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This collection of information does not provide for payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

A request for review of a scientific controversy may contain trade secret and confidential commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by Section 301(j) of the FFDCA, and by part 20 of our regulations (21 CFR part 20). Information and records from respondents are kept in a secure building and in secured files.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden for 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

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

In the next 3 years, CVM anticipates receiving no more than one request for review of a scientific dispute per year. Our estimate is based on our on experience with the information collection over the past 6 years.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer or Consultant ¹	40	\$43.90	\$1,756

¹ May 2016 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

CVM has allocated the equivalent of 5 FTEs to its scientific dispute resolution process, including an Ombudsman and authorized Center managers who may decide the outcome of a scientific controversy. The Ad Hoc Appeals Committee involves a minimum of an additional 3 FTEs. Using 2018 data from OPM for a GS-15/Step 1 in the Washington DC Metropolitan area (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf>), we multiplied \$134,789 by 8 FTEs for an estimated cost of \$1,078,312.

15. Explanation for Program Changes or Adjustments

The information collection reflects an adjustment by 40 burden hours and 4 annual responses for an overall reduction. We have reduced our estimate based on the number of annual submissions over the past 6 years, and hope this underscores the effectiveness of our guidance in resolving scientific disputes within CVM.

16. Plans for Tabulation and Publication and Project Time Schedule

Information will not be published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.