UNITED STATES FOOD AND DRUG ADMINISTRATION

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

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, us or we) guidance. CVM's 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.

We therefore request OMB extension of OMB approval of the following citation and GFI #79, "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine":

21 CFR 10.75 – Reporting

Establishes that a sponsor, applicant, or manufacturer of a product regulated by the Center for Veterinary Medicine may request review of a scientific controversy.

2. Purpose and Use of the Information Collection

This information will be submitted by sponsors, applicants, or manufacturers, who request review of a scientific controversy relating to a decision affecting animal drugs or other products that are regulated by CVM.

The purpose of collecting this information is to facilitate the resolution of such disputes and promote greater use of alternative dispute resolution techniques including mediation, arbitration, and neutral intervention by the CVM Ombudsman.

3. Use of Improved Information 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 estimate that, in any given year, our one estimated respondent will use electronic means to communicate with us and submit his or her request for review.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Respondents to this collection of information are sponsors, applicants, or manufacturers who submit information to request review of a scientific controversy relating to a decision affecting animal drugs or other products that are regulated by CVM. These firms may be small businesses or larger concerns. 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. Resources for small business assistance can be found on our website at https://www.fda.gov/animal-veterinary/resources-you/cvm-small-business-assistance. We estimate that, in any given year, our one estimated respondent could be a small business.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. If this information is 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. This would make the resolution process more difficult.

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

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

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

FDA published a 60-day notice for public comment in the *Federal Register* of August 18, 2020 (85 FR 50827). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is work contact information such as name, work address, work telephone number, and work email address. This information collection describes the process by which CVM formally resolves disputes relating to scientific controversies. 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 FD&C Act, and by part 20 of our regulations (21 CFR part 20). Through appropriate instruction, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1. – Estimated Annul Reporting Burden[1]

21 CFR Part	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.

12b. Annualized Cost Burden Estimate

Burden hour measurements should reflect differences in the value of a diverse range of personnel resources. To properly value these personnel, each agency is to develop burden hour estimates for each of four categories of labor:

(a) clerical and other unskilled workers;
(b) skilled and craft-labor and other technical workers;

(c) professionals and managers; and
(d) executives.

All wages rates need to be fully-loaded, i.e., reflect the full cost of labor including fringe benefits.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer or Consultance[1]	40	51.84	$2,073.60

[1]May 2019 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/oes/current/oes131041.htm).

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

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

14. Annualized Cost to the Federal Government

There is one FTE for the CVM Ombudsman who handles the dispute resolution process, 2 FTEs for the Division Director and the Office Director and 2 FTEs for the Deputy Center Director and the Center Director who decide the outcome of a scientific controversy. The Ad Hoc Appeals Committee would involve a minimum of an additional 3 FTEs. Scientific disputes resolved at a lower level in the chain of command generally only involve the FTEs for the Division Director and the Office Director. The cost of each FTE is roughly $142,701 (an average compensation rate of a GS-15, Step 1 for 2020) for a total of $1,141,608 for approximately 8 FTEs.

15. Explanation for Program Changes or Adjustments

We have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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.