Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)

OMB CONTROL NO. 0910-0566
SUPPORTING STATEMENT

Terms of Clearance: None.

Part A. Justification

1. Circumstances Making This Information Collection Necessary

This guidance document describes CVM's policy for resolution of disputes relating to scientific controversies. A scientific controversy involves issues that arise within the context of the Center's regulation of a specific product and are related to matters of technical expertise that require some specialized education, training, or experience to be understood and resolved. The guidance document #79 describes the dispute resolution procedures that we recommend be followed by sponsors, applicants, and manufacturers when requesting review of FDA decisions related to regulated products for animals.

The specific citation within 21 CFR Part 10 regarding information collection requirements for which we request OMB approval is:

21 CFR 10.75 (b)(2) Internal Agency Review of Decisions

Section 404 of the Food and Drug Modernization Act of 1997 (FDAMA) amends the Federal, Food, Drug and Cosmetic Act (the act) by adding a provision (section 562) for dispute resolution. 21 CFR 10.75 was amended to allow the FDA centers to develop and administer their own processes for handling requests for reviews of scientific controversies. This guidance sets forth CVM's processes.

This information collection does not relate to the American Recovery and Reinvestment Act of 2009.

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

N/A.

4. Efforts to Identify Duplication and Use of Similar Information

This information is not collected by any other agency in the Government. The information collection required by 21 CFR 10.75(b)(2) does not duplicate any other information collection.

5. Impact on Small Businesses or Other Small Entities

FDA's dispute resolution procedures and their accompanying collections of information benefit small businesses as well as larger business concerns because they lead to informal ombudsman intervention, mediation and/or arbitration of disputes, which will result in time and money saved by not litigating these issues. This reduces the burden of compliance on businesses by allowing a forum for discussion and resolution of scientific controversies in accordance with a May 1, 1998, Presidential memorandum which sought to encourage the use of alternative means of dispute resolution within the Federal government.

6. Consequences of Collecting the Information Less Frequently

If this information is not collected, CVM and the CVM Ombudsman will not be able to assess accurately the scientific controversy under dispute and this will make the resolution process more difficult. The information is collected only for the purpose of evaluating and deciding on the scientific issues in dispute and may not be collected less frequently.

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

The information collection is consistent with 5 CFR 1320.5 and 5 CFR 1320.6.

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

On November 6, 2014 (79 FR 65976), FDA published in the Federal Register, a 60-day notice of extension of information collection 0910-0566 entitled, "Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)." The public was given until January 5, 2015, to submit comments on the extension of the information collection. One comment was received which was not responsive to the request for comment on the information collection and was outside the scope of this information request.

9. Explanation of any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information and records from respondents are kept in a secure building and in secured files first within the keeping of the Division Director and the Office Director, then within the CVM Ombudsman's keeping and finally within the keeping of the Deputy Center Director and the Center Director for requests for review by the Ad Hoc Appeals Committee and by an advisory committee respectively.

11. Justification for Sensitive Questions

This information does not contain questions pertaining to any matter commonly considered private or of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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	2	4	8	10	80

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer or Consultant	80	$30	$2400

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

N/A.

14. Annualized Cost to the Federal Government

The Dispute Resolution process involves potentially mediation and negotiation with staff at all levels of CVM with widely varying rates of compensation or FTEs. This includes the Division and Office Directors up to other senior level management. Each appeal is unique and many do not reach the highest level because they are settled at a lower level in the chain of command.

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 $126,000 (an average compensation rate of a GS-15, Step 1 for 2015) for a total of $1,008,000 for approximately 8 FTEs.

15. Changes from Previous Approval

This estimated annual reporting burden is based on CVM's experience over the past 3 years in handling formal appeals for scientific disputes. The number of respondents increased from 1 to 2 annually, the frequency of response increased from 3 to 4 annually, the hours per response remained at 10 annually, and the total number of hours increased from 30 to 80. This small increase in the total hourly burden is the result of a natural fluctuation in the number of respondents taking advantage of this dispute resolution process.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of this information collection are not to be published.

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

FDA will display the OMB approval date.

18. Explanations to Section 19, "Certification for Paperwork Reduction Act Submissions."

There are no exceptions.