OMB CONTROL NO>
SUPPORTING STATEMENT

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

Part A. Justification

1. Circumstances Which Make 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 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 citations within 21 CFR Part 10 regarding information collection requirements for which we request OMB approval are:

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 and takes into consideration relevant comments received in response to the proposed rule for §10.75.

2. How, by Whom, and the Purpose for Collecting This Information

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 informal 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 Technology to Reduce the Burden on the Public

N/A.

4. Identification and Use of Duplicate 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. FDA's Efforts to Reduce Burden on Small Business

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. Impact of Not Collecting This Information or Collecting 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 Agency

On March 26, 2008 (73 FR 16021), FDA published in the Federal Register, a 60 day notice of extension of an information collection OMB # 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 May 27, 2008, to submit comments on the extension of the information collection. No comments were received on the collection of information.

9. Explanation of any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. **Assurance of Confidentiality Provided to Respondent**

Information and records from respondents are kept in a secure building and in secured files first within the CVM Ombudsman's keeping and then within the keeping of the Deputy Center Director and the Center Director for requests for review by the Ad Hoc Appeals Committee and by the Veterinary Medicine Advisory Committee (VMAC) respectively.

11. **Use of Sensitive Questions**

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

12. Burden Hours and Cost Associated With This Collection

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Guidance	2	4	8	10	80

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

13. **Estimate of Other Total Cost Burden to Respondents and Recordkeepers**

The estimates of cost burden have been addressed in item 12. No other cost burdens are associated with the collection of this information.

14. Annual Cost Estimate to FDA

There is one FTE for the CVM Ombudsman who handles the dispute resolution process 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 additional 3 FTEs. The cost of each FTE is $115, 000 for a total of $690,000 for 6 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 2 to 4 annually,

the hours per response decreased from 30 to 10 annually, and the total number of hours increased from 60 to 80 hours.

16. Publishing the Results of this Information Collection

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

17. Reason for Not Displaying the OMB Approval Date

FDA will display the OMB approval date.

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

There are no exceptions.

Part B. Collections of Information Using Statistical Methods

Not applicable.