

OMB0910-0451
SUPPORTING STATEMENT
PRESUBMISSION CONFERENCES

A. Justification

1. Circumstances Which Make This Information Collection Necessary

Under the Federal, Food, Drug and Cosmetic Act (the Act), as amended by the Animal Drug Availability Act of 1996 (ADAA), any person intending to file a new animal drug application or supplemental new animal drug application or to investigate a new animal drug is entitled to one or more conferences with FDA to reach an agreement establishing a submission or investigational requirement. This Final Rule describes how a person would request a presubmission conference and describes the procedures for the conduct and documentation of the presubmission conference.

We are requesting OMB approval of the information collection requirements contained in the following specific citations in 21 CFR Part 514.5.

(b) – Reporting

Specifies the information a potential applicant must submit to FDA when the potential applicant requests a presubmission conference, including a proposed agenda and a list of expected participants.

(d) – Reporting

Specifies the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference,

(f)(iii) Reporting

Provides the potential applicant an opportunity to submit a request for correction or clarification of the memorandum of conference prepared by FDA.

The purpose of a presubmission conference is to reach an agreement establishing a submission or investigational requirement.

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

The regulation establishes the procedures for requesting, conducting and documenting presubmission conferences. Presubmission conferences give FDA and a potential applicant a means to identify the least burdensome appropriate requirements that have a reasonable likelihood of resulting in approval.

3. Use of Technology to Reduce the Burden on the Public

We do allow drug sponsors to submit certain information in electronic format for review if resources and technology permit.

4. Identification and Use of Duplicate Information

There are no other regulations or Federal Agencies that require the submission of the same type of information. There is no similar data/information that could be substituted for that required by these regulations.

5. FDA's Efforts to Reduce Burden on Small Business

The collection of information carries the same burden for small as for large firms. The law and corresponding regulations governing requesting, conducting and documenting presubmission conferences will be applied consistently and equally to all enterprises. While we cannot establish different standards with respect to statutory requirements, we do provide special help to small businesses. A small business coordinator has been established on the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep our management apprised of how its regulatory decisions may impact the small business community.

6. Impact of Not Collecting This Information or Collecting Information Less Frequently

Industry and FDA will not be able to hold productive meetings to reach binding agreements regarding investigational or submission requirements.

7. Special Circumstances That Occur When Collecting This Information

There are no special circumstances for the collection of the information requirements.

8. Identification of Outside FDA Sources

Prior to the enactment of the ADAA, CVM had already been encouraging sponsors of NADAs to participate in conferences with FDA to discuss in detail what studies are necessary to demonstrate the safety and effectiveness of the particular new animal drug being investigated. FDA and industry found that, as a result of this direct communication during the development and review of new animal drugs, both the drug development and review processes became more efficient. To the extent that this rule educates those in the industry that were not familiar with presubmission conferences, there will be further benefits as

additional potential applicants realize efficiencies gained in the animal drug development and application process if they request a presubmission conference. Further, the procedures for requesting a presubmission conference will help to ensure that the presubmission conferences are productive.

On August 25, 2000 (65 FR 51782), a 60 day notice for public comment on the collection of information was published in the Federal Register. Four comments were received from government, industry and trade associations. None commented on this collection of information.

9. Payment or Gifts Offered to Respondents

No payment or gift is provided to respondents.

10. Method of Ensuring Respondent Confidentiality

Information will be kept confidential in accordance with 18 USC 1905 and 21 USC 331(j), as well as Section 301 (j) of the Act.

11. Use of Sensitive Questions

This information does not contain questions pertaining to sex behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12. Burden Hours Associated With This Information Collection

The estimated annual burden for this information collection is 27,740 hours.

Estimated Annual Reporting Burden ¹

21 CFR	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
514.4(b)	190	1	190	7	1330
514.4(d)	190	1	190	123	23370
514.4(f)	190	1	190	16	3040
Total Hours					27740

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

13. Annual Cost Estimate to Respondents

There are no annual costs estimates to the respondents.

14. Annual Cost Estimate to FDA

Total cost estimate to FDA is \$304,000. This is based on an average of 32 hours spent for each of the 190 estimated conferences at an average of \$50 per hour (32 x 190 x \$50 = \$304,000).

15. Changes from Previous Approval

Not previously approved. Assigned OMB Comment number 0910-0451

16. Publishing the Results of This Information Collection

Information is not published for statistical use.

17. Reason for Not Displaying the OMB Approval Date

FDA is not seeking approval of an exemption from displaying the expiration date for OMB approval.

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

There are no exceptions to Item 19 of OMB Form 83-I.