OMB Control Number 0910-0452

SUPPORTING STATEMENT

GUIDANCE FOR INDUSTRY ON HOW TO USE E-MAIL TO SUBMIT A REQUEST FOR A MEETING OR TELECONFERENCE TO THE OFFICE OF NEW ANIMAL DRUG EVALUATION

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

As part of NAD development, sponsors often meet with CVM scientists to formulate a rational approach to studies to be conducted and to discuss how to meet the statutory requirements for drug approval under Section 512 of the Federal Food, Drug, and Cosmetic Act. Requests for meetings and teleconferences about NAD submissions were previously submitted on paper copy to CVM.

The specific citations within 21 CFR 500 regarding information collection requirements for which we request OMB approval are:

21 CFR 10.65 - Meetings and correspondence

Meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner.

2. Purpose and Use of the Information

CVM holds meetings and/or teleconferences to assist sponsors with NAD submissions and general questions. Such meetings and teleconferences are a courtesy to sponsors initiated at their request. Previously, meeting and teleconference requests were submitted to CVM on paper. CVM now allows sponsors to request meetings and teleconferences in a manner more efficient and time saving to them. This guidance gives sponsors the option to submit a request for a meeting or teleconference as an e-mail attachment by the Internet.

3. Use of Information Technology and Burden Reduction

In the Federal Register of March 20, 1997 (62 FR 13430), the FDA published the Electronic Records, Electronic Signatures final regulation. This regulation (21 CFR 11) provides for the voluntary submission of parts or all of regulatory records in electronic format without an

accompanying paper copy. This rule also established public docket number 97S-0251 to provide a permanent location for a list of the documents or parts of the document that are acceptable for
submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify electronic submission of requests for meetings and teleconferences in this public docket as a submission type which may be made in electronic format.

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 as a result of 21 CFR 511.1(b)(5) does not duplicate any other information collection.

5. Impact on Small Business or Other Small Entities

There is no impact on small business or other small entities.

6. Consequences of Collecting the Information Less Frequently

The information required under these regulations must be developed for each meeting or teleconference to the Office of New Animal Drug Evaluation. There is no time schedule for information collection. The frequency is set by the manufacturer production schedule.

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

The reporting requirements are consistent with 5 CFR 1320.5.

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

In the Federal Register of November 8, 2006 (71 FR 65535) FDA published a notice providing a 60 day comment period on this information collection. In response to that notice, no comments were received.

9. Explanation of Any Payment or Gifts to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

During working hours, only FDA employees have access to the computer files and database on a need to know basis. During duty and non-duty hours building security is provided through a contract with a private protection agency. None of these provisions bar the release of the confidential information if subpoenaed by a court of law. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act. Further, under the terms of the Freedom of Information Act, the sponsor's name, address, and phone number reported on FDA Form 3489 cannot be made available to a public request.

11. Justification for 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. Estimates of Hour Burden Including Annualized Hourly Costs

ESTIMATED ANNUAL REPORTING BURDEN[a]

21 CFR Section No./ FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(1)// Form FDA 3489	25	6.24	156	.08	12.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]A middle manger salary at $35/hour.

The estimates in the above table result from discussions with new animal drug sponsors. The estimated burden includes requests for meetings or teleconferences submitted by e-mail and on paper.

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

CVM used a wage rate of $35.00 per hour, and multiplied times the total hour burden estimated above (12.5), the total cost burden to respondents is $437.5 (12.5 hours X $35/hour).

14. Annualized Cost to the Federal Government

The cost to the federal government to receive and file notices (paper copy or e-mail) would be the essentially the same cost of burden to industry. A wage rate of $35.00 per hour is used and multiplied times the total hour burden estimated above (12.5 hours), the total cost to the Federal government is $437.5 (12.5 hours X $35/hour).

15. Explanation of Program Changes or Adjustments

There was a decrease (adjustment), in the number of burden hours based on FDA's review of submissions submitted from from July 1, 2005 to June 20, 2006 and from previous discussions with sponsors regarding the time necessary to fill out this form.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.