Supporting Statement

Guidance for Industry #88 on How to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation (ONADE)
OMB Control #0910-0452

1. Circumstances Making the Information Collection Necessary

Any person intending to file a new animal drug application or abbreviated application is entitled to request meetings and/or teleconferences to reach agreement regarding a submission or investigational requirement (21 USC 360b(b)(3)). Every person outside the Federal Government may request a meeting with representatives of FDA to discuss a matter (21 CFR 10.65(c)). Sponsors often meet with scientists in CVM/ONADE to formulate a rational approach to studies to be conducted and to discuss how to meet the statutory requirements for new animal drug approval under Section 512 of the Federal, Food, Drug and Cosmetic Act.

This guidance document describes the procedure for persons to submit a request for a meeting or teleconference electronically on FDA Form #3489.

2. Purpose and Use of the Information Collection

CVM holds meetings and/or teleconferences to assist sponsors with new animal drug submissions and general questions. Such meetings and teleconferences are a courtesy to sponsors initiated at their request. Previously, meetings 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 as an e-mail attachment via the Internet.

3. Use of Improved Information Technology and Burden Reduction

The electronic submission of requests for meetings and teleconferences is part of CVM's ongoing initiative to provide a method for paperless submissions. This is in accordance with 21 CFR Part 11, which provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. Currently 46% of sponsors are submitting requests for meetings or teleconferences electronically.

4. Efforts to Identify Duplication and Use of Similar Information

This information is not collected by any other Agency in the Federal government. The information 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

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 regulatory decisions might impact the small business community. Furthermore, we encourage sponsors, whether large or small businesses, to meet with the Center for Veterinary Medicine.

6. Consequences of Collecting the Information Less Frequently

The information required under these regulations must be developed for each meeting or teleconference with ONADE. There is no time schedule for information collection. The frequency is set by the manufacturer's 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 the Agency

In the **Federal Register** of February 5, 2010, (75 FR 6035), FDA published a notice providing a 60-day comment period on this information collection. Two comments were received. One was completely outside the scope of the notice and the other requested that FDA meet openly with industry rather than in closed sessions. Neither comment addressed the paperwork involved in the information collection.

9. Explanation of Any Payment or Gift 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 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 Federal, Food, Drug and Cosmetic Act. Further, under the terms of the Freedom of Information Act, the sponsor's name, address, and phone number reported on FDA Form 3488 cannot be made available to a public request.

11. Justification for Sensitive Questions

This information collection does not contain questions commonly considered private or of a sensitive nature.

12a. Annualized Burden Hour Estimate

Table 1.—Annual Reporting Burden[1]

21 CFR 10.65/Form FDA 3489	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
	40	2.4	96[2]	.08	7.7

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in Table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses is the actual number of such submissions made between January 1, 2008, and December 31, 2008. (96 x hours per response (.08)) = 7.7 total hours.

12.b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs
Industry compliance officer	7.7	$38	$293

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

There are no other costs to respondents.

14. Annualized Cost to the Federal Government

The cost to the Federal government to receive this notice would be a wage rate for an average level reviewer (GS-13) $43 times 7.7 hours (the hourly burden to review is essentially the same hours as for industry) equals $331.

14. Explanation of Program Changes or Adjustments

[1] 2006 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (www.bls.gov/oes/current/naics4_325400.htm) $29.27 hourly wage plus 30% adjusted for benefits

There was a decrease (adjustment) in the total number of responses and burden hours due to the annual variation in the number of notices received.

15. Plans for Tabulation and Publication of Project Time Schedule

Information is not to be published for statistical use.

16. Reasons Display of OMB Expiration Date is Inappropriate

Display is not inappropriate.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification