OMB CONTROL Number 0910-0524
SUPPORTING STATEMENT

Guidance for Industry: How to Use E-mail to Submit a Protocol

A. Justification

1. Circumstances Making the Information Collection Necessary

Protocols for non-clinical laboratory studies (safety studies) are required under 21 CFR 58.120 for approval of new animal drugs. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Upon request by the animal drug sponsors, CVM reviews protocols for safety and effectiveness studies. Establishing a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of new animal drug applications (NADA's) is part of the Center for Veterinary Medicine (CVM's) ongoing initiative to provide a method for paperless submissions. Currently, sponsors submit protocols to CVM in paper format. CVM is publishing this guidance to give sponsors the option to submit a protocol as an e-mail attachment via the Internet. This guidance implements provisions of the Government Paperwork Elimination Act (GPEA). The GPEA requires Federal agencies, by October 21, 2003, to provide (1) for the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitution for paper; and (2) for the use and acceptance of electronic signatures, where applicable.

FDA is seeking new paperwork clearance for form FDA 3536 to facilitate the use of electronic submission of protocols.

This collection of information is for the benefit of animal drug sponsors, giving them the flexibility to submit data for review via the Internet.

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

Animal drug sponsors will submit this information as part of the application process for a new animal drug.

The purpose of gathering this information is to provide greater flexibility in the animal drug approval process for the benefit of sponsors. Sponsors are permitted to submit data regarding protocols via electronic submission, if they so desire.

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

CVM is accepting electronic safety and efficacy protocols via electronic submission in accordance with the GPEA.

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 514.1(b) does not duplicate any other information collection.

5. **FDA's Efforts to Reduce Burden on Small Businesses**

The option of electronic submission allows businesses large and small to take advantage of the greater efficiency of submitting data and information in the most convenient format for sponsors of new animal drug applications.

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

The information to be collected is necessary to process the electronic submission of protocols and is intended to make the drug application process more efficient. The use of electronic submission is optional but gives the animal drug industry the ability to supply required application information in the most convenient and appropriate manner.

7. **Explain any Special Circumstances That Occur When Collecting the Information**.

There are no special circumstances that occur when collecting this information.

8. Identification of Outside FDA Sources.

FDA published a 60-day notice in the **Federal Register** on November 8, 2006 (71 FR 65534) requesting comment on the collection of information. In response to that notice, no comments were received.

9. **Explanation of any Payment or Gift to Respondents**

There are no payments or gifts to respondents.

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

Laws and regulations protect the disclosure of the existence of an Investigational New Animal Drug (21 CFR 514.12), the disclosure of an NADA

(21 CFR 514.11), and the disclosure of trade secret and confidential commercial information (section 301(j) of the Federal Food, Drug and Cosmetic Act, the Freedom of Information Act, and the Trade Secrets Act).

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

ESTIMATED ANNUAL REPORTING BURDEN

Form FDA #	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
3536	25	.4.2	103	.20	20.6

[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

This collection of information will not result in any further costs to FDA than is incurred in the current NADA approval process.

15. Changes from Previous Approval

The number of burden hours were based on FDA's review of submissions submitted from July 1, 2005 to June 20, 2006 and from previous discussions with sponsors regarding the time necessary to fill out this form.

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.