OMB Control Number 0910-0454

SUPPORTING STATEMENT

GUIDANCE FOR INDUSTRY ON HOW TO USE E-MAIL TO SUBMIT INFORMATION TO THE CENTER FOR VETERINARY MEDICINE

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

The Center for Veterinary Medicine (CVM) accepts certain types of submissions by e-mail with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. This guidance outlines general standards to be used for the submission of any information by e-mail.

The specific citations regarding information collection requirements for which we request OMB approval are:

21 CFR 11.2 - Reporting
21 CFR 11.2 requires that the Agency identify in the Electronic Submissions Docket the types of documents or parts of documents acceptable for official electronic submission.

2. Purpose and Use of the Information

This guidance document describes the procedures for persons who are sponsors of new animal drugs who wish to file submissions by e-mail. Persons filing information electronically agree to follow the criteria as outlined in the guidance document. The guidance instructs those who wish to submit information to CVM by e-mail to first register with the Center. Registration entails sending a letter to CVM with a sponsor password and the names, phone numbers, and mail and e-mail addresses of a Sponsor Coordinator and any person who will submit information electronically to CVM. A letter is sent on paper and electronically. Other information collection provisions described in this guidance are submission of e-mails with the individual passwords of those who submit information electronically and e-mails with any changes to the sponsor's registration. CVM will use all the information submitted to process electronic submissions. The likely respondents to this collection of information are new animal drug sponsors.

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.

4. Efforts to Identify Duplication and Use of Similar Information

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

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

Information will be collected only twice. First, the sponsor will register by sending a letter to CVM with a sponsor password and the names, phone numbers, and mail and e-mail addresses of a Sponsor Coordinator and any person who will submit information electronically to CVM. This letter is sent on paper and electronically. The other information collection is submission of e-mails with the individual passwords of those who submit information electronically and e-mails with any changes to the sponsor's registration.

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 65533) 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

CVM needs certain information to ensure the confidentiality, integrity, security and authentication of data submitted to the Center in electronic format by e-mail. This information includes the sponsor password that will be used by all of the people who will submit information electronically on the sponsor's behalf, and individual passwords that will be used exclusively by each individual. Use of the sponsor password to encrypt information sent by e-mail will help assure the security of submissions. Use of the individual password together with an individual e-mail address will constitute an electronic signature. (see 21 CFR 11.200(a)(v).)

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	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
21 CFR 11.2	25	5.62	140	.08	11.2

[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.

Estimates from this table resulted from discussions with new animal drug sponsors.

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 (11.2 hours), the total cost burden to respondents is $392 (11.2 hours X $35/hour).

14. Annualized Cost to the Federal Government

The cost to the federal government to receive and file information (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 (11.2 hours), the total cost to the Federal government is $392 (11.2 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 July 1, 2005 to June 20, 2006 and from previous discussions with sponsors regarding the time necessary to complete information.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.