# Guidance for Industry #107 on How to Submit a Protocol Without Data in Electronic Format to CVM

OMB No. 0910-0524

# Supporting Statement

## A. Justification

1. Circumstances Making the Collection of Information Necessary--Abstract

New animal drugs are approved under Section 512 of the Federal Food, Drug and Cosmetic Act. Protocols for nonclinical laboratory studies (safety studies) are required under section 512 of the act and 21 CFR 58.120 for approval of new animal drugs. Protocols for adequate and well-controlled effectiveness studies are required under Section 512 of the act and 21 CFR 514.117(b).

2. Purpose and Use of the Information Collection

CVM's guidance on how to submit a study protocol without data as an e-mail attachment via the Internet is in accordance with the Government Paperwork Elimination Act. FDA Form 3536 is used to facilitate the use of electronic submission of protocols.

3. Use of Improved Information Technology and Burden Reduction

The electronic submission of protocols 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. Approximately 36% of the protocol submissions from March 1, 2009 through April 1, 2010 were submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

Information is collected from the sponsor as an e-mail attachment to CVM. This information is not duplicated by any other government agency.

5. Impact on Small Businesses or other Small Entities.

We believe that the law and regulations apply to all persons equally. While we do not believe we can apply different standards with respect to statutory requirements, we do provide special help to small business. 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 new animal drug application submissions. There is no time schedule for the information collection. The frequency is set by the animal drug sponsor.

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 accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the **Federal Register** on February 18, 2010 (75 FR 7278). One comment was received. It was outside the scope of the notice.

9. Explanation of any Payment or Gift to Respondents

There were no payments or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

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.

11. Justification for Sensitive Questions

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

12.a. Estimates of Annualized Burden and Costs

Table 1.—Estimated Annual Reporting Burden1

| Section of the act/CFR/FDA Form # | No. of Respondents | Annual Frequency Per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 512/ 21 CFR 514,117(b), 21 CFR 58.120/#3536 | 40 | 1.8 | 72[2] | .2 | 14.4 |

[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.

12.b. Annualized Cost Burden Estimate

| Type of Respondent | Total Burden Hours | Hourly Wage Rate[1] | Total Respondent Costs |
|---|---|---|---|
| Industry compliance officer | 14.4 | $38 | $547 |
| | | | |

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 and file protocols would be a wage rate for an average level reviewer (GS-13) $43 times 14.4 hours (the hourly burden to review is essentially the same hours as for industry) equals $619.

15. Explanation of Program Changes or Adjustments

There was a decrease in the total number of responses due to annual variation in the protocols received, thus resulting in a decrease in the burden estimate.

16. Plans for Tabulation and Publication of Project Time Schedule

Information is not to be published for statistical use.

17. Reasons Display of OMB Expiration Date is Inappropriate

Display is not inappropriate.

[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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.