Guidance for Industry #108
How to Submit Information in Electronic Format to CVM
Using the FDA Electronic Submission Gateway--21 CFR 11.2
OMB Control Number 0910-0454--Extension

Supporting Statement A

1. Circumstances Making the Collection of Information Necessary

The Electronic Submission Gateway is part of the Center for Veterinary Medicine's (CVM) ongoing initiative to provide a method for electronic 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. These types of documents are listed in public docket 92S-0251 (subsequently changed to FDA-1992-S-0039) as required by 21 CFR 11.2.

CVM's guidance entitled "Guidance for Industry #108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway," outlines how to register with CVM's Electronic Submission System (ESS). 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.

Form FDA 3538.

2. Purpose and Use of the Information Collection

CVM's guidance on how to submit information in electronic format to CVM using the FDA Electronic Submission Gateway is in accordance with the Government Paperwork Elimination Act. Form FDA 3538 is used to facilitate the use of electronic submission of such information. The likely respondents are sponsors of new animal drug applications.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates 100% of these notices are submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

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 businesses. A small business coordinator has been established on the Commissioner's staff to ensure that small businesses have an adequate opportunity to express 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 must be developed by animal drug sponsors. 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 May 16, 2013 (78 FR 28851). No comments were received.

9. Explanation of any Payment or Gift to Respondents

There are 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. Estimates of Annualized Burden Hours and Costs

12a. Estimate of Annualized Hour Burden

Table 1.—Estimated Annual Reporting Burden[1]

CFR Section; FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR 11.2; Form FDA 3538	65	2.4	156	.08	13 (Rounded from 12.48)

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Estimate of Annualized Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs
Industry compliance officer	13	$39	$507

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 is determined by multiplying the wage for an average level reviewer (GS-13) using the Washington Area Pay Scale by the total number of burden hours, such that: $43 times 13 hours equals $559.

15. Explanation of Program Changes or Adjustments

There was an increase of 140 in the total number of responses due to annual variation in the number of notices received. This resulted in an annual burden increase of 11 hours.

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.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

[1] 2012 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, 13-1041 Compliance Officer (www.bls.gov/oes/current/naics4_325400.htm) $29.82 hourly wage plus 30% adjusted for benefits.