Guidance for Industry on
How to Submit Information in Electronic Format to CVM
Using the FDA Electronic Submission Gateway

0910-0454

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

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 FDA-1992-S-0039 as required by 21 CFR 11.2. Our ability to receive and process information submitted electronically is limited by our current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. Our guidance entitled ''Guidance for Industry #108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway'' outlines general standards to be used for the submission of any electronic information to CVM using the FDA ESG, including how to register with CVM's Electronic Submission System (ESS).

We request extension of OMB approval of the information collection requirements in the following citations; in Form FDA 3538, Electronic Submission System Participant Management Form; and in Guidance #108:

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 Collection

The reporting associated with NADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the FD&C Act. We use the information collected to review the data, labeling and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug. Respondents use Guidance #108 and Form FDA 3538 to facilitate the electronic submission of such information. The respondents are sponsors of new animal drug applications. Respondents are private sector, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

We currently accept this information electronically via the ESG. We estimate that 100% of the submissions will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

The information provided in accordance with Guidance #108 and Form FDA 3538 is unique to the particular sponsor and particular product covered by the application. This information is not duplicated by any other government agency.

5. Impact on Small Businesses or Other Small Entities

Because of the critical nature of the products, their uses and the impact on the consumer or user, any submission of an application for approval of a new animal drug from a small business concern is treated with the same rigorous scientific and technical review as that submitted by a large pharmaceutical firm. However, we assist small businesses to meet the part 514 requirements through FDA's Regional Small Business Representatives and through the scientific and administrative staff within the Center. We estimate that one or fewer businesses would be small businesses.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. 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.There are no special circumstances for this collection of information.

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 April 8, 2016 (81 FR 20647). We received one comment, but it did not pertain to the information collection.

9. Explanation of any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

We expect that an application will contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section

301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

	Table 1.—Estimated Annual Reporting Burden					
21 CFR section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
11.2	3538	29	1.3	38	.08 (5 minutes)	3.0

We base our estimates on our experience with the submission of electronic information to us using the FDA ESG and the number of electronic registration or change requests received between January 1, 2014 and December 31, 2015.

12b. Annualized Cost Burden Estimate

We estimate the total annualized cost burden to be $129.72.

Table 2.--Annualized Cost Burden			
Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs
Industry compliance officer	3	$43.24	$129.72

[1] 2015 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, 13-1041 Compliance Officer (www.bls.gov) $33.26 hourly wage plus 30% adjusted for benefits ($33.26 + 30% = $43.24).

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

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 locality pay area of Washington-Baltimore in 2016 pay scale by the total number of burden hours, such that: $43.52 x 3 hours = $130.56.

15. Explanation for Program Changes or Adjustments

There was a decrease in the total number of responses due to annual variation in the number of notices received. This resulted in an annual burden decrease of 118 responses and 9 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate and publish information from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.