U.S. Food and Drug Administration
Guidance for Industry on Registering with the Center for Veterinary Medicine's Electronic Submission System

OMB Control Number 0910-0454

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA's Electronic Records; Electronic Signatures regulation (21 CFR part 11) requires that we identify in the Electronic Submission Docket (Docket No. FDA-1992-S-0039) the types of documents or parts of documents acceptable for official electronic submission. FDA's CVM has placed notifications in that docket identifying documents acceptable for electronic submission to the Center, 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 FDA's Electronic Records; Electronic Signatures regulation.

The FDA Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review. The FDA ESG is the central transmission point for sending information electronically to FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office. CVM's Electronic Submission System (ESS) is a Center-wide solution for accepting electronic regulatory submissions. The CVM ESS is used to accept electronic submissions for animal and veterinary products.

Our Guidance for Industry (GFI) #108 entitled, "Registering with the Center for Veterinary Medicine's Electronic Submission System," outlines general standards to be used for the submission of any electronic information to CVM using the FDA ESG, including how to register with the CVM ESS using Form FDA 3538, Electronic Submission System Participant Management Form. Registering with the CVM ESS allows respondents to send electronic regulatory submissions to the Office of New Animal Drug Evaluation (ONADE), the Office of Surveillance and Compliance's (OSC) Division of Animal Feeds (DAF) and Division of Surveillance (DS), and the Office of Minor Use and Minor Species Animal Drug Development (OMUMS).

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 GFI #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

Respondents use GFI #108 and Form FDA 3538 to facilitate the electronic submission of regulatory information. We use the information collected with Form FDA 3538 to register respondents to use the CVM ESS. The respondents are submitters of regulatory information to CVM. Respondents are private sector for-profit businesses and not-for-profit institutions, and Federal, State, Local or Tribal Governments.

3. Use of Improved Information Technology and Burden Reduction

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

4. Efforts to Identify Duplication and Use of Similar Information

The information provided in accordance with GFI #108 and Form FDA 3538 is unique to the particular sponsor. 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 to CVM 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. There is no time schedule for the information collection. The frequency is set by the entity wishing to submit regulatory information to CVM.

7. Special Circumstances Relating to the Guidelines of 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* of April 16, 2019 (84 FR 15621). No comments were received.

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

    This information collection request (ICR) is collecting personally identifiable information (PII). PII is collected in the context of the individuals' professional capacity. The PII submitted for Form FDA 3538 (Electronic Submission System Participant Management) is name, company name, company address, telephone number, and email address. This ICR involves registering to use CVM's electronic submission system.

    FDA further determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

    In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

    We expect that regulatory information 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	FDA 3538	193	1.3	251	.08 (5 minutes)	20

We base our estimates on our experience with the submission of electronic information using the CVM ESS and the number of electronic registration or change requests received between January 1, 2018, and December 31, 2018.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer	20	$51.82[1]	$1,036.40

[1] 2018 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, 13-1041 Compliance Officer (www.bls.gov), $39.86 hourly wage plus 30% adjusted for benefits ($39.86+30% = $51.82).

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-Arlington, DC-MD-VA-WV-PA in 2019 pay scale by the total number of burden hours, such that: $47.52 x 20 hours = $950.40.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 17 hours and a corresponding increase of 213 responses. We attribute this adjustment to the reauthorizations of both the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act, which require sponsors to submit information electronically to CVM's Office of New Animal Drug Evaluation. Because of this requirement, sponsors are now registering to use the CVM ESS in greater numbers than in previous years.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.