U.S. Food and Drug Administration

Substances Prohibited from Use in Animal Food or Feed

OMB Control No. 0910-0627

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations regarding substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent and presents particular risks to the public health. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. To implement certain public health protection provisions of the Federal Food, Drug, and Cosmetic Act, as amended, we have codified regulations at 21 CFR Part 589 (Substances prohibited from use in animal food or feed) to further strengthen existing safeguards against the transmission and spread of BSE in the United States through animal feed.

Specifically, requirements under 21 CFR 589.2001: *Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy* prohibit the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as "*cattle materials prohibited in animal feed*" or CMPAF. To demonstrate compliance with the regulatory requirements respondents must maintain certain records. Also under 21 CFR 589.2001, FDA may designate a country as not subject to the requirements. A country seeking such a designation must submit a written request that includes specific information about BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, as well as any other relevant information.

We therefore request extension of the approval for the information collection requirements found under 21 CFR 589.2001.

2. Purpose and Use of the Information Collection

The information collection is used to implement public health protection provisions of the act designed to prevent the transmission and spread of BSE. We use the recordkeeping information to determine industry compliance with the regulatory requirements. Information reported to FDA is used in determining whether a country may be designated as not subject to the regulation in accordance with specific requirements.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical or other technological techniques or other forms of information technology to fulfill the information collection requirements. Respondents may utilize information technology as desired and we estimate fifty percent (50%) will use electronic means to keep the required records.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. However, a review of our inventory suggests that the information collection may be combined with OMB Control No. 0910-0339: *Substances Prohibited from Use in Animal Food or Feed*, which accounts for the burden associated with information collection under 21 CFR Part 589.2000 (*Animal proteins prohibited in ruminant feed*). This related collection expires October 31, 2019, before which time FDA will evaluate both collections to see whether consolidation is appropriate.

5. Impact on Small Businesses or Other Small Entities

We believe approximately thirty to fifty percent (30-50%) of respondents are small businesses; however we believe the information collection poses no undue burden on small entities. At the same time, FDA aids small businesses in complying with its requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at: http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements and applicable regulations.

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 in the Federal Register of November 3, 2017 (82 FR 51279). Four comments were received in response to the notice but were not discussed in our 30 day notice of February 26, 2018 (83 FR 8287). We regret this oversight. None of the comments suggested we revise our estimate of the burden associated with the information collection and all comments supported enforcement of the underlying regulation. Finally, one comment provided us with reference to a confirmed case of BSE and underscored the importance of the information collection. We appreciate these comments and, regarding the feedback as positive, have retained our current estimate as discussed more fully below at Question 12 of this Supporting Statement.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of information is safeguarded within the provisions of FDA's public information regulations in 21 CFR Part 20.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

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

12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Part 589.2001; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
589.2001(c)(2)(ii); maintain written procedures	50	1	50	20	1,000
589.2001(c)(2)(vi) and (c)(3)(i); maintain records	175	1	175	20	3,500
589.2001(c)(3)(i)(A) and (B); certification or documentation from the supplier	175	1	175	26	4,550
Total					9,050

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

Our estimate of the recordkeeping burden associated with the information collection is based on our experience since implementation of the regulatory requirements set forth in our final rule of April 25, 2008 (73 FR 22720 at 22753). Although somewhat dated, we find no basis on which to revise our estimate at this time.

Table 2.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
589.2001(f); request for designation	1	1	1	80	80
589.2001(f); response to request for review by FDA	1	1	1	26	26

Table 2.--Estimated Annual Reporting Burden[1]					
21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Total					106

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

Similarly, our estimate of the reporting burden for designation under § 589.2001(f) is based on estimates found in our final rule. Since the rule's effective date in 2009, only two requests for designation have been received; however we retain our current estimate of 1 to permit such requests for designation by respondents.

12 b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer[1]	106	$43.90	$4,653.40

[1] 2016 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes131041.htm) $33.77 hourly wage plus 30% adjusted for benefits.

As reflected above, the regulation allows a country to submit an application requesting a designation as not being subject to the restrictions on the use of CMPAF. Using the total number of hours for annual reporting (106 hours) multiplied by an hourly wage for an industry compliance officer ($43.90), the estimated cost to respondents is $4,653.40.

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

Costs to the Federal Government were calculated by using 2018 OPM wage rates for a GS-13-Step 4 employee in the Washington-Baltimore area ($51.11/hour) and multiplying this figure by the number of FTE hours FDA might expend on the review of designation requests under the regulation. Total estimated costs are therefore $3424.37.

15. Explanation for Program Changes or Adjustments

We have retained the currently approved burden for the information collection.

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.