United States Food and Drug Administration

Substances Prohibited from Use in Animal Food or Feed

OMB Control No. 0910-0627

SUPPORTING STATEMENT

Terms of Clearance: None

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration 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. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. Our regulation at § 589.2001 (21 CFR 589.2001) entitled, "Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy," is designed to further strengthen existing safeguards against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits 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. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements on renderers of specifically defined cattle materials, including reporting and recordkeeping requirements. For purposes of the regulation, we define a renderer as any firm or individual that processes slaughter byproducts, animals unfit for human consumption, including carcasses of dead cattle, or meat scraps.

We therefore request OMB extension of OMB approval of the information requirements found in 21 CFR 589.2001 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Under our regulations, we may designate a country from which cattle materials are not considered CMPAF. Section 589.2001(f) provides that a country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine. The information the country is required to submit includes information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in § 589.2001(b)(1). We use the information to determine whether to grant a request for designation and to impose conditions if a request is granted. Section 589.2001(f) further states that countries designated under that section will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a

country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate. We use the information to ensure their designations remain appropriate.

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.

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: https://www.fda.gov/industry/small-business-assistance

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

FDA published a 60-day notice for public comment in the *Federal Register* of December 17, 2020 (85 FR 81930). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name, telephone number, and email address. The information collected allows foreign countries to request an

exemption from 21 CFR 589.2001 and domestic firms who need to demonstrate compliance when someone (FDA or state) comes to do an inspection. Through appropriate information collection, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Part	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
Total					106

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

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.

Table 2 – Estimated Annual Recordkeeping Burden[1]

21 CFR Part	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.

Similarly, 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.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer[1]	106	$45.54	$4,827.24

[1]2019 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes131041.htm) $ $35.03 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 ($45.54), the estimated cost to respondents is $4,827.24.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 2021 OPM wage rates for a GS-13-Step 4 employee in the Washington-Baltimore area ($54.65/hour) and multiplying this figure by the number of FTE hours (67 hours) FDA might expend on the review of designation requests under the regulation. Total estimated costs are therefore $3,661.55

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

This information collected will not be published or tabulated.

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.