United States Food and Drug Administration
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed
OMB Control No. 0910-0339

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 (FDA, us or we) regulations. Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. Regulation 21 CFR 589.2000 provides that animal protein derived from mammalian tissue (with some exclusions) is not generally recognized as safe (GRAS) for use in ruminant feed and is a food additive subject to certain provisions of the FD&C Act. This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain, or may contain, protein derived from mammalian tissue, and feeds made from such products.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution, and who intend to separate mammalian and nonmammalian materials in their facility, to maintain written procedures specifying the cleanout procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize consistent processes, and then to help inspection personnel confirm that the firm is conducting these processes in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained if the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by this section shall be made available for inspection and copying by FDA.

We therefore request OMB extension of OMB approval of the information collection provisions found in 21 CFR 589.2000 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

These written procedures are intended to help the firm formalize consistent processes, and then to help inspection personnel confirm that the firm is conducting these processes in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being

followed when they are conducting an inspection. These written procedures must be maintained as long as the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by 21 CFR 589.2000(e)(1)(iv) shall be made available for inspection and copying by FDA.

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 as necessary for use by firms. Firms are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. We estimate that ninety-five percent (95%) of the recordkeepers 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

Assuming that about ten percent of the respondents are small businesses, we estimate that approximately 23 of the 225 respondents reported in table 1 are small businesses. The recordkeeping provisions are no more burdensome for small firms than for large. The regulations require all affected parties to maintain the same records. The recordkeeping requirements are based on the risk associated with the product. FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA also provides a Small Business Guide on the Agency's website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

The records are kept on an occasional basis. If there is no requirement to keep these records, as there is no end-product testing available, the agency will have only limited means to monitor compliance. Without the ability to monitor compliance, the health of animals and the public may be put at risk.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with 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 January 28, 2022 (87 FR 4626). Although one comment was received, it was not responsive to the four collection of information topics solicited.

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 does not collect personally identifiable information (PII) or information of a personal nature. The regulation requires firms involved in feed and feed ingredient manufacturing and distribution to prepare written standard operating procedures for handling protein derived from mammalian tissue. Because the FDA does not collect PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

Information submitted to FDA may contain trade secret and commercial confidential information. 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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

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

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Written procedures; 589.2000(e)(1)(iv)	225	1	225	14	3,150

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

We base our estimate of the number of recordkeepers on inspectional data. Based on a review of the information collection since our last request for OMB approval we have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Review of our inspection data suggests that the number of facilities that need to conduct these separation practices is gradually decreasing, therefore we have decreased the number of facilities who must comply, as well as the total number of hours needed to comply with this burden.

12b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents is equivalent to a GS-11-7 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2022, approximately $43.09/hour. Increasing this wage by 30% to account for overhead costs

($12.93 (rounded)), FDA estimates the average hourly cost to respondents to be $56.02/hour. The overall estimated cost incurred by the respondents is $176,463 (3150 burden hours x $56.02/hr = $176,463).

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

We estimate the annualized cost to the Federal government for the inspection of records to be $16,785. We estimate that we expend approximately 300-person hours annually in inspections. The estimated number of inspections each year is 75 and the estimated total number of hours per inspection spent on reviewing records is 4 hours (75 inspections x 4 hours = 300 hours annually). We estimate the average hourly wage for personnel to complete an inspection and review to be at the GS-12 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2022, approximately $43.04/hour. Increasing this wage by 30% to account for overhead costs ($12.91), we estimate the average hourly wage to be $55.95. The estimated annualized cost to the Federal government is $16,785 (300 hours x $55.95 = $16,785).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval we have adjusted our burden estimate, which has resulted in a decrease of 1,330 burden hours. Review of our inspection data suggests that the number of facilities that need to conduct these separation practices is gradually decreasing, therefore we have decreased the number of facilities who must comply, as well as the total number of hours needed to comply with this burden.

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

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.