Substances Prohibited from Use in Animal Food or Feed;
Animal Proteins Prohibited in Ruminant Feed

0910-0339

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act. Our regulation at 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 (62 FR 30936, June 5, 1997).

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 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 request extension of OMB approval of the recordkeeping requirement in the following citation:

21 CFR 589.2000(e)(1)(iv) - Recordkeeping

Requirement specifying written procedures be developed and maintained to ensure separation of mammalian protein from non-mammalian protein intended for use in ruminant feed.

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.

4. Efforts to Identify Duplication and Use of Similar Information.

There are no other regulations or Federal agencies that require the development and maintenance for recordkeeping of this nature.

5. Impact on Small Business or Other Small Entities

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/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of December 21, 2018 (83 FR 65681). We received one comment in support of

the regulation.

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 ICR is not collecting personally identifiable information (PII) or other data 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.

In preparing this supporting statement, FDA staff consulted with the FDA Privacy Office. FDA determined that PII is not collected and the Privacy Act of 1974 does not apply.

With regard to confidentiality, this information collection requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution 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. FDA expects that it may inspect such firm records from time to time and that these records may contain confidential commercial information. To the extent 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes. In addition, 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)). All records and reports maintained by FDA are kept in limited access areas.

11. Justification for Sensitive Questions.

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

12. Estimates of Annualized Burden Hours and Costs

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)	320	1	320	14	4,480

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

We base our estimate of the number of recordkeepers on inspectional data.

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 in 2019, approximately $39.12/hour. Increasing this wage by 30% to account for overhead costs ($11.74), FDA estimates the average hourly cost to respondents to be $50.86/hour. The overall estimated cost incurred by the respondents is $227,852.80 (4480 burden hours x $50.86/hr = $227,852.80).

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

We estimate the annualized cost to the Federal government for the inspection of records to be $59,468.80. We estimate that we expend approximately 1,280-person hours annually in inspections. The estimated number of inspections each year is 320 and the estimated total number of hours per inspection spent on reviewing records is 4 hours (320 inspections x 4 hours = 1280 hours annually). We estimate the average hourly wage for personnel to complete an inspection and review to be at the GS-13 level in the locality pay area of Washington-Baltimore in 2019, approximately $46.46/hour. The estimated annualized cost to the Federal government is $59,468.80 (1280 hours x $44.00 = $59,468.80).

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

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

17. Reasons 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.