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

0910-0339

SUPPORTING STATEMENT

Terms of Clearance: None.

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 Act. Our regulation at 21 CFR 589.2000 provide 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 act (62 FR 30936).

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, the 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.

We request 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 their processes, and then to help inspection personnel confirm that the firm is operating 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 have the option of using information technology if they wish. FDA estimates 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.

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

FDA estimates that approximately 32 or fewer respondents would qualify as 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.

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

All of the reporting requirements are consistent with 5 CFR 1320.5.

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 March 15, 2016 (81 FR 13803). We received one comment but it did not pertain to the information collection.

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 will be 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 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

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	4480

We base our estimates on our experience with similar requirements to maintain written procedures. We base our estimate of the number of recordkeepers on inspectional data, which reflect a decline in the number of recordkeepers. We attribute this decline to a reduction in the number of firms handling animal protein for use in animal feed.

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 2016, approximately $37.17/hour. Increasing this wage by 30% to account for overhead costs ($11.15), FDA estimates the average hourly cost to respondents to be $48.32/hour. The overall estimated cost incurred by the respondents is $216,473.60 (4480 burden hours x $48.32/hr = $216,473.60).

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 $56,320. 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 2016, approximately $44.00/hour. The estimated annualized cost to the Federal government is $56,320 (1280 hours x $44.00 = $56,320).

15. Explanation for Program Changes or Adjustments

We base our estimate of the number of recordkeepers on inspectional data, which reflect a decline in the number of recordkeepers. We attribute this decline to a reduction in the number of firms handling animal protein for use in animal feed.

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

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.