SUPPORTING STATEMENT

OMB Control No. 0910-0339

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

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (the act) gives us the authority to issue regulations for the efficient enforcement of the act. On June 5, 1997, we issued a final rule which amended 21 CFR 589.2000 to 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).

We took this action because epidemiological evidence gathered in the United Kingdom suggests 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 rule 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.

This is a request for 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.

This information collection is not related to the American Recovery and Investment Act of 2009.

2. Purpose and Use of the Information

These records would be subject to inspection by Federal and State agencies to ensure that ruminant feed does not contain protein derived from mammalian tissues. Records must be retained for a 2 year minimum period.

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.

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.

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

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

A 60-day notice published in the Federal Register on May 16, 2013 (78 FR 28,852), soliciting public comments on the recordkeeping requirements placed on handlers of ruminant proteins, to ensure separation of mammalian protein from non-mammalian protein intended for use in ruminant feed. In response to that notice, no comments were received.

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 any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs.

12a. Annualized Hour Burden Estimate

Firms (renderers, blenders, and feed manufacturers and distributors) that handle animal protein products from both mammalian and non-mammalian sources, and that intend to keep the products separate, have certain requirements related to their source of mammalian material; the need for separate facilities or cleanout procedures; and the need for standard operating procedures (SOPs). Similar requirements would apply to firms that handle feeds containing animal protein products from both mammalian and non-mammalian sources, and that intend to keep the feeds separate.

The recordkeeping burden in the following table has been estimated using the typical average size establishment that handles animal protein from both mammalian and non-mammalian sources, or feeds containing these products, which in both instances, are kept separate. Our estimate of the number of record keepers that separate mammalian and non-mammalian materials is derived from inspectional data of firms handling animal protein for use in animal feed. The annualized hourly burden for recordkeeping under 21 CFR 589.2000 (e)(1)(iv) is estimated as follows:

Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
589.2000(e)(1)(iv)	400	1	400	14	5600

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer	5600	$38	$212,800

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers/Capital Costs

There are no additional costs associated with this collection of information.

14. Annualized Cost to the Federal Government

Records would be inspected during the agency's normal course of business, either during routine or for-cause inspections. In addition, some of these inspections would be carried out under contract or in partnership with state agencies. The estimated number of inspections each year is 400 and the estimated total number of hours per inspection spent on reviewing records is 4 hours. By multiplying 400 inspections x 4 hours at the rate of $43/hr. (the wage rate for a GS-13 employee), the agency estimates the annual cost to government to be $68,800.

15. Explanation of Program Changes or Adjustment

There is no change in burden.

16. Plans for Tabulation and Publication and Project Time Schedule

N / A

17. Reasons display of OMB expiration date is inappropriate

N / A

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.