Substances Prohibited from Use in Animal Food or Feed (21 CFR Part 589)

SUPPORTING STATEMENT
OMB Control No. 0910-0627

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. The rule placed 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.

We took this action 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. While BSE had yet to be diagnosed in the United States, measures were necessary to prevent the establishment and amplification of this fatal disease in this country and thereby minimize any risk which might be faced by animals and humans.

In 2003, two cows tested positive for BSE, one in Canada and the other in the state of Washington. An epidemiological investigation and DNA test results confirmed that the Washington state cow was born and most likely became infected in Alberta, Canada, prior to Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants. Several BSE positive cows were found in Canada from 2004-2006; in June of 2005, a 12-year-old beef cow, born and raised in Texas, tested positive for BSE. This was the first instance of BSE infection of a cow native to the United States.

The cases of BSE detected in Canada and the United States provide evidence of the risk of BSE in North America. The U.S. and Canadian feed bans implemented in 1997 were intended to address uncertainty about whether BSE was present in the cattle population of either country. While we continue to believe that compliance with the feed regulation has provided strong protection against the spread of BSE, the agency believes that the recent cases are an indication that additional animal feed protections are needed. Therefore, we believe that it was appropriate to propose certain additional measures in October 2005. More than 800 comments were received from industry, trade associations, government entities, and consumers. The final rule, which published April 25, 2008 (73 FR 22720), prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials include the following: (1) the entire carcass of bovine

spongiform encephalopathy (BSE)-positive cattle; (2) the brains and spinal cords from cattle 30 months of age and older; (3) the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not removed; (4) tallow that is derived from BSE-positive cattle; (5) tallow that is derived from other materials prohibited by this rule that contains more than 0.15 percent insoluble impurities; and (6) mechanically separated beef that is derived from the materials prohibited by this rule.

This is a request for OMB approval of the following information collection requirements:

21 CFR 589.2001 (c)(2)(ii) and (vi)- Recordkeeping – Requirement for renderers that manufacture, process, blend or distribute cattle materials prohibited in animal feed (CMPAF) or products that contain or may contain CMPAF to maintain adequate written procedures specifying how they remove brain and spinal cord from cattle not inspected and passed for human consumption, or how they separate such animals based on whether or not they are 30 months of age or older. Renderers in this category must also maintain records sufficient to track CMPAF to ensure such material is not introduced into animal feed. Records are to be made available for FDA inspection and copying, and are to be retained for a minimum of 1 year.

21 CFR 589.2001 (c)(3)(i) – Recordkeeping – Requirement for renderers that manufacture, process, blend or distribute any cattle materials, to establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with or does not otherwise contain CMPAF. For renderers that receive cattle materials from a supplier, such records are considered sufficient if they include either (1) certification or other documentation from the supplier that material supplied to the renderer does not include CMPAF, provided that it includes a description of the segregation procedures used, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderers periodic review of the suppliers' certification or other documentation; or (2) Documentation of another method acceptable to FDA, such as third-party certification, for verifying that suppliers have effectively excluded CMPAF. Records are to be made available for FDA inspection and copying, and are to be retained for a minimum of 1 year.

21 CFR 589.2001(c)(3)(i) (A) and (B) – Recordkeeping
Documentation of another method acceptable to FDA, such as third party certification, for verifying that suppliers have effectively excluded CMPAF. Records are to be made available for FDA inspection and copying and are to be retained for a minimum of 1 year.

21 CFR 589.2001(b)(1) and 21 CFR 589.2001(f)—Reporting— Requirement that any foreign country seeking a designation from FDA that such country, due to a low BSE risk in that country, is not subject to the restrictions applicable to CMPAF must submit a written request to the agency. The written request has to include sufficient scientific evidence to support the claimed BSE risk status.

2. Purpose and Use of the Information Collection

These records are subject to inspection by Federal and State agencies to ensure that animal food or feed does not contain protein which may cause the spread of BSE in this country.

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 of recordkeeping of this nature.

5. Impact on Small Business or Other Small Entities

The reporting & 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 are no requirements for reporting and recordkeeping, the Agency will have 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 Guideline 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 in the Federal Register of November 21, 2014 (79 FR 69493). One comment was received; however, it did not respond to any of the four information collection topics solicited and is, therefore, not addressed by the agency. At the same time, upon closer examination by the agency, we have eliminated the operating and maintenance costs associated with the recordkeeping requirements that were identified in both our 60-day and 30-day Federal Register notices. These costs reflect costs associated with implementation of the recordkeeping requirements and we believe that they have now been realized since the effective date of the rule (April 27, 2009).

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.

FDA estimates the burden for this information collection as follows:

12a. Annualized Burden Hour Estimate

Table 1- Estimated Annual Reporting Burden[1]

21 CFR Section 589.2001(f)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Respondent	Total Hours
One-time (initial) burden	1	1	1	80	80
Burden from future review	1	1	1	26	26

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

There is a one-time reporting burden to countries that apply to FDA seeking to be designated as not subject to the restrictions applicable to CMPAF (§589.2001(b)(1) and §589.2001(f)). We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 1, row 1, of this document presents the one-time burden expected for countries that apply for the exclusion, and row 2 of the Table shows the recurring burden.

Table 2 -. Estimated Annual Recordkeeping Burden [1]

21 CFR Section 589.2001; Substances Prohibited from Use in Animal Food or Feed	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeper	Total Hours
589.2001(c)(2)(vi) and (c)(3)(i)	175	1	175	20	3,500
589.2001 (c)(2)(ii)	50	1	50	20	1,000
589.2001(c) (3)(i)(A)	175	1	175	26	4,550
TOTAL					9,050

[1]There are no capital costs or operating and maintenance costs associated with this burden

The recordkeeping requirement in §589.2001(c)(2)(vi) applies to a limited number of renderers who handle prohibited bovine material. We estimate that no more than 50 of the approximately 175 rendering firms are involved in the handling of this material. Although we may consider the distribution records needed to comply with this regulation "usual and customary" and thus not subject to the PRA, we believe there is a burden associated with setting up a system to ensure such records are sufficient to address the proposed recordkeeping requirement. Likewise, although we may consider the records necessary to comply with §589.2001(c)(3)(i) as "usual and customary" and not subject to the PRA, we are including a burden estimate to cover establishment of a system to ensure existing receipt and manufacturing records adequately address this requirement.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer	106	$38	$4,028

As indicated in Table 1 above, this regulation provides for a country to submit an application requesting a designation as not being subject to the restrictions on the use of CMPAF. FDA estimates the hour burden costs to respondents choosing to submit a request for designation to be $4,028. We calculated this estimate by multiplying the total burden of 106 hours times the hourly wage of a compliance officer ($38), the private employee equivalent to which we believe best represents the approximate cost of preparing and submitting the request for designation.

13. Estimate of Other Total Cost Burden to Respondents

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The regulation requires the expenditure of additional funds by the Federal or State government, but the increased expenditures are not significant. The tissues that are included on the list of cattle materials prohibited in animal feed due to this regulation increase the number of inspections or the length of time necessary to inspect an establishment to verify compliance with the new requirements. However, the number of establishments inspected is not substantially changed as a result of this rule. All establishments that are inspected for compliance under §589.2001 are already subject to §589.2000 or other Federal rules.

However, the regulation requires some additional cost to the government for the review of the estimated 1 original applications from foreign governments for country exclusion designation and 1 recurring annual review of such exclusion designations. The estimated time for reviewing and evaluating these applications by FDA personnel is approximately 50 hours per original application and approximately 17 hours for recurring annual review

of exclusion designations. Therefore, the cost to the Federal Government is estimated to be $3,350 (67 hours times $50/hour—the average GS-13 wage rate).

15. Explanation of Program Changes or Adjustments

The total burden for this collection has been adjusted to reflect that the number of countries submitting an application requesting a designation as not being subject to the restrictions on the use of CMPAF has decreased, as has the number of recurring annual reviews of exclusion designations. This has resulted in an overall decrease to the collection by **958** hours. Also, upon closer examination by the agency, we have eliminated the operating and maintenance costs associated with the recordkeeping requirements that were identified in both our 60-day and 30-day Federal Register notices. These costs reflect costs associated with implementation of the recordkeeping requirements and we believe that they have now been realized since the effective date of the rule (April 27, 2009).

16. Plans for Tabulation and Publication and Project Time Schedule

Not applicable.

17. Explain the reasons that display of the expiration date for OMB approval of the information collection would be inappropriate

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Submissions

There are no exceptions to the certification.