

UNITED STATES FOOD & DRUG ADMINISTRATION

Substances Prohibited from Use in Animal Food or Feed

OMB Control No. 0910-0339 -- Revision

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory and regulatory requirements. 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. 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). Epidemiological evidence gathered in the United Kingdom has 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.

FDA regulation in 21 CFR 589.2000 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 are revising the information collection to include related activity currently approved and account for in OMB control no. 0910-0627. Specifically, our regulation at 21 CFR 589.2001 is designed to safeguard against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as “cattle materials prohibited in animal feed” or CMPAF. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements to maintain adequate written procedures and recordkeeping on renderers that receive, manufacture, process, blend, or distribute raw material

from cattle and to make these records available for inspection and copying by FDA to demonstrate they are taking measures to ensure that CMPAF is not introduced into animal feed. Additionally, under § 589.2001(f), we may designate a country from which cattle materials are not considered CMPAF. A country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine, including certain required information. We use the information provided to determine whether to grant a request for designation and to impose conditions if a request is granted. Designated countries will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries at any time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate.

We therefore request OMB approval for the information collection provisions found in 21 CFR 589.2000 and 589.2001, 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 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 15 of the 150 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. Additionally, we provide a Small Business Guide on our website at <http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm>.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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 the *Federal Register* of June 27, 90 FR 27630, we published a 60-day notice soliciting public comment on the proposed collection of information. Two comments were received but did not respond to the information collection topics solicited under 5 CFR 1320.8(d)(2). At the same time, on our own initiative we also corrected an inadvertent error appearing in our 60-day notice regarding our burden adjustment found at Q-12.

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

The Privacy Act of 1974

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.

Freedom of Information Act (FOIA)

Under FOIA, 5 U.S.C. 552, 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*

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR 589 - Substances Prohibited From Use in Animal Food or Feed	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Written procedures (prohibited animal proteins); 589.2000(e)(1)(iv)	150	1	150	12	1,800
Exemption designation requests & response to FDA; 589.2001(f)	1	2	2	33	66
Written procedures (prohibited materials to prevent BSE) & maintenance of records	145	1	145	45	6,525
TOTAL			0		0

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

12b. *Annualized Cost Burden Estimate*

We assume an average hourly wage for respondents equivalent to a GS-12-7 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2025, \$58.31/hour. Increasing this wage by 30% to account for overhead costs (\$17.49), we calculate average hourly cost to respondents to be \$75.80/hour. When factored by the total burden hours we calculate an annual cost to respondents of \$136,440 (1800 burden hours x \$75.80/hr = \$136,440).

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 \$22,740. We assume 300-person hours are expended annually in inspections, an average of 75 inspections annually, and 4 hours for review (75 inspections x 4 hours = 300 hours annually). We further assume an average hourly wage for personnel to complete an inspection and review commensurate with wages for a GS-12-7 level employee in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2025, \$58.31/hour. Increasing this wage by 30% to account for overhead costs (\$17.49), we factor the average hourly wage of \$75.80 by the total annual hours to calculate an annual cost of \$22,740 (300 hours x \$75.80 = \$22,740).

15. Explanation for Program Changes or Adjustments

The information collection reflects program changes and adjustments. We have decreased the number of respondents to provisions in 21 CFR 589.2000, however, in consolidating related activity currently approved in 0910-0627 there is an overall increase in annual burden by 72 responses and 5,241 hours.. Upon OMB review and approval we intend to discontinue control. no. 0910-0627.

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.