4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0354]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited from Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Prohibited From Use in Animal Food or Feed

OMB Control Number 0910-0339--Revision

This information collection supports implementation of statutory and regulatory requirements. 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. Agency regulation at § 589.2000 (21 CFR 589.2000), authorized by section 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(a)), 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). The 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, § 589.2000(e)(1)(iv) 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. Consistent with § 589.2000(h), written procedures shall be made available for inspection and copying by FDA, and records made available for inspection and copying by FDA must be retained for 1 year.

Description of Respondents: Respondents include renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution.

In the *Federal Register* of September 2, 2025, 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). We also note an inadvertent calculation error which we have corrected.

At the same time, on our own initiative and for efficiency of Agency operations, we are revising the information collection to include related activity currently approved and accounted 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 estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

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			297		8,391

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

We characterize all collection activity as recordkeeping noting that a recordkeeping requirement, as defined by 5 CFR 1320.3(m), includes the requirement to retain, disclose, and report the information, including reporting the information to the Federal government.

We base our estimate of the number of recordkeepers on inspectional data. Upon evaluation, we have adjusted our burden estimate to reflect a decrease of 1,350 hours annually to the currently approved burden applicable to prohibited animal protein records required by 21 CFR 589.2000. Review of our inspection data suggests that the number of facilities that need to conduct these separation practices is gradually decreasing. These facilities are well aware of the requirements established in the BSE rule (https://www.fda.gov/food/hfp-constituent-updates/fda-announces-final-rule-bovine-spongiform-encephalopathy). Compliance with the rule's requirements also helps facilitate compliance with the requirements of the Food Safety Modernization Act Preventive Controls in Animal Food rule (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food) requiring every firm to have a written food safety plan. The written procedure required by the BSE rule could be used as part of a facility's food safety plan. Regardless, the number of facilities subject to this portion of the BSE rule is decreasing and therefore, we have decreased the number of facilities who must comply, as well as the total number of hours needed to comply with this burden.

We have retained the annual burden estimate that we attribute to activities under 21 CFR 589.2001 (147 responses, 6,591 hours) and currently approved in OMB control no. 0910-0627. We intend to discontinue the later control no. from our inventory upon OMB review and approval.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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