

To obtain approval for an individual generic collection submission that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (e.g., a copy of the survey or experimental design and stimuli for testing).

FDA will submit individual quantitative collections under this generic clearance to OMB. Individual quantitative collections will also undergo review by FDA's Research

Involving Human Subjects Committee, senior leadership in the Center for Food Safety and Applied Nutrition, and PRA specialists.

Respondents to this collection of information may include a wide range of consumers and other FDA stakeholders, such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

In the **Federal Register** of September 9, 2021 (86 FR 50544), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and, therefore, will not be discussed in this document.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN BY ANTICIPATED DATA COLLECTION METHODS ¹

Survey type	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per response	Total hours
Cognitive Interviews Screener	720	1	720	0.083 (5 minutes)	60
Cognitive Interviews	144	1	144	1	144
Pre-test Study Screener	2,400	1	2,400	0.083 (5 minutes)	199
Pre-test Study	480	1	480	0.25 (15 minutes)	120
Self-administered Surveys/Experimental Studies Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-administered Surveys/Experimental Studies	15,000	1	15,000	0.25 (15 minutes)	3,750
Total	10,498

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The total estimated annual burden is 10,498 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: January 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-01730 Filed 1-27-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0520]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements regarding animal proteins prohibited in ruminant feed.

DATES: Submit either electronic or written comments on the collection of information by March 29, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 29, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 29, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets

Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2013-N-0520 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the

docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR 589.2000(e)(1)(iv)

OMB Control Number 0910-0339—Extension

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).

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, 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.

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

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Written procedures; 589.2000(e)(1)(iv)	300	1	300	14	4,200

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

We base our estimate of the number of recordkeepers on inspectional data. Based on a review of the information collection since our last request for OMB approval we have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Review of our inspection data suggests that the number of facilities that need to conduct these separation practices is gradually decreasing, 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.

Dated: January 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-N-0742; FDA-2018-N-0180; FDA-2019-N-2854; FDA-2021-N-0515; FDA-2014-N-1960; FDA-2017-D-6069; and FDA-2019-N-3325]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food

and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910-0045	12/31/2024
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910-0810	12/31/2024
Premarket Tobacco Product Applications and Recordkeeping Requirements	0910-0879	12/31/2024
Postmarketing Adverse Experience Reporting and Recordkeeping	0910-0230	1/31/2025
MedWatch: Adverse Event and Product Experience Reporting System (Paper Based)	0910-0291	1/31/2025
De Novo Classification Process (Evaluation of Automatic Class III Designation)	0910-0844	1/31/2025
Laboratory Accreditation for Analyses of Foods	0910-0898	1/31/2025

Dated: January 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board) is authorized under Section 319M of the

Public Health Service (PHS) Act, as added by Section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by Section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act. The Board is governed by the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The NBSB provides expert advice and guidance on scientific, technical, and other matters of special interest to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. Authority to manage and operate the NBSB, including to receive advice and

recommendations from the Board, has been delegated by the Secretary of HHS to the Assistant Secretary for Preparedness and Response (ASPR). The NBSB will meet in public (virtually) on March 7, 2022, beginning at 12:30 p.m. Eastern time. ASPR invites stakeholders and the general public to attend and participate as appropriate. A detailed agenda and instructions to register to attend the meeting will be available on the NBSB meeting website <https://www.phe.gov/nbsb>.

Procedures for Public Participation: Members of the public may attend the meeting via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting link to pre-register will be posted on the meeting website <https://www.phe.gov/>