



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@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; 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 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 their processes, and then to help inspection personnel confirm that the firm is operating 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 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.

In the *Federal Register* of December 21, 2018 (83 FR 65681), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received in support of the collection of information.

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

Table 1.--Estimated Annual Recordkeeping Burden<sup>1</sup>

| 21 CFR Section; Activity               | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 589.2000(e)(1)(iv); written procedures | 320                  | 1                               | 320                  | 14                               | 4,480       |

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

We base our estimates on our experience with similar requirements to maintain written procedures. 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 made no adjustments to our burden estimate.

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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