



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0510]

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: 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. All comments should be identified with the OMB control number 0910-0627. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, 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: 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--21 CFR 589.2001

OMB Control Number 0910-0627--Extension

This information collection supports Agency regulations regarding substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. Our regulation at § 589.2001 (21 CFR 589.2001) entitled "Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy" is designed to further strengthen existing safeguards 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 on renderers of specifically defined cattle materials, including reporting and recordkeeping requirements. For purposes of the regulation, we define a renderer as any firm or individual that processes slaughter byproducts, animals unfit for human consumption, including carcasses of dead cattle, or meat scraps. Reporting and recordkeeping requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know whether the cattle material meets the requirements of our regulation.

Recordkeeping: Renderers that receive, manufacture, process, blend, or distribute CMPAF, or products that contain or may contain CMPAF, must take measures to ensure that the

materials are not introduced into animal feed, including maintaining adequate written procedures specifying how such processes are to be carried out (§ 589.2001(c)(2)(ii)). Renderers that receive, manufacture, process, blend, or distribute CMPAF, are required to establish and maintain records sufficient to track the CMPAF to ensure that they are not introduced into animal feed (§ 589.2001(c)(2)(vi)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must 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 (§ 589.2001(c)(3)(i)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must, if these materials were obtained from an establishment that segregates CMPAF from other materials, establish and maintain records to demonstrate that the supplier has adequate procedures in place to effectively exclude CMPAF from any materials supplied (§ 589.2001(c)(3)(i)). Records will meet this requirement if they include either: (1) certification or other documentation from the supplier that materials supplied do not include CMPAF (§ 589.2001(c)(3)(i)(A)) or (2) documentation of another method acceptable to FDA, such as third-party certification (§ 589.2001(c)(3)(i)(B)).

Reporting: Under our regulations, we may designate a country from which cattle materials are not considered CMPAF. Section 589.2001(f) provides that a country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine. The information the country is required to submit includes information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting

country do or do not meet the definitions set forth in § 589.2001(b)(1). We use the information to determine whether to grant a request for designation and to impose conditions if a request is granted. Section 589.2001(f) further states that countries designated under that section will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries from time to 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 use the information to ensure their designations remain appropriate.

Description of Respondents: Respondents to this information collection include rendering facilities, feed manufacturers, livestock feeders, and foreign governments seeking designation under § 589.2001(f).

In the *Federal Register* of November 3, 2017 (82 FR 51279), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received four comments, which were not responsive to the four collection of information topics solicited, and therefore will not be discussed in this document.

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

Table 1.--Estimated Annual Recordkeeping Burden¹

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 589.2001(c)(2)(ii), maintain written procedures | 50 | 1 | 50 | 20 | 1,000 |
| 589.2001(c)(2)(vi) and (c)(3)(i), maintain records | 175 | 1 | 175 | 20 | 3,500 |

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 589.2001(c)(3)(i)(A) and (B), certification or documentation from the supplier | 175 | 1 | 175 | 26 | 4,550 |
| Total | | | | | 9,050 |

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

Except where otherwise noted, this estimate is based on our estimate of the number of facilities affected by the final rule entitled "Substances Prohibited From Use in Animal Food or Feed" published in the *Federal Register* of April 25, 2008 (73 FR 22720 at 22753). The estimated recordkeeping burden is derived from Agency resources and discussions with affected industry. Our regulations require the maintenance of certain written procedures if cattle not inspected and passed for human consumption are to be rendered for use in animal feed. The recordkeeping burden associated with the requirement to maintain written procedures (§ 589.2001(c)(2)(ii)) will apply to only those renderers that choose to render for use in animal feed cattle not inspected and passed for human consumption. The recordkeeping requirement in § 589.2001(c)(2)(vi) will apply to the limited number of renderers that will handle CMPAF. We estimate that the recordkeeping burden associated with § 589.2001(c)(3)(i) would apply to the balance of the rendering firms not handling CMPAF. Table 1 also reflects the estimated 26 hours each renderer will need to satisfy the requirement in § 589.2001(c)(3)(i)(A) and (B) under which renderers must maintain records from their supplier, certifying that materials provided were free of CMPAF.

Table 2.--Estimated Annual Reporting Burden¹

| 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 589.2001(f); request for designation | 1 | 1 | 1 | 80 | 80 |
| 589.2001(f); response to request for review by FDA | 1 | 1 | 1 | 26 | 26 |

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

Our estimate of the reporting burden for designation under § 589.2001(f) is based on estimates in the final rule entitled "Substances Prohibited From Use in Animal Food or Feed" published in the *Federal Register* of April 25, 2008, our experience, and the average number of requests for designation received in the past 3 years. The reporting burden for § 589.2001(f) is minimal because requests for designation are seldom submitted. Since 2009, we have received two requests for designation. In the last 3 years, we have not received any new requests for designation; therefore, we estimate that one or fewer requests for designation will be submitted annually. Although we have not received any new requests for designation in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a foreign government to request designation under § 589.2001(f). Table 2, row 1, presents the expected burden of requests for designation. Countries designated under § 589.2001(f) are subject to review by FDA to ensure that their designation remains appropriate. We assume a country's response to a request for review will take about one third the time and effort of a request for designation. Table 2, row 2, presents the expected burden of a request for review. The burden for this information collection has not changed since the last OMB approval.

Dated: February 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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