Dated: March 26, 2021.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

[FR Doc. 2021–06740 Filed 3–31–21; 8:45 am]

**BILLING CODE 4154–01–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

**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 May 3, 2021.

**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 0910–0627. 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, *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—21 CFR Part 589

*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.

*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 country is required to submit information about its 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.

*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)).

*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 December 17, 2020 (85 FR 81930), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR part | Number of respondents | Number 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 |
| Total | | | | | 106 |

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

TABLE 2—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 |
|---|---|---|---|---|---|
| 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 |
| 589.2001(c)(3)(i)(A) and (B); certification or documentation from the supplier | 175 | 1 | 175 | 26 | 4,550 |
| Total | | | | | 9,050 |

[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.

Dated: March 26, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–06706 Filed 3–31–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–E–1314]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; IBSRELA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for IBSRELA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by June 1, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 28, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

**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 June 1, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 1, 2021. 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 d89.pelivery/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.''