

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: November 16, 2020.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1677]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle

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 December 28, 2020.

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 0910-0623. 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, 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.

Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle—21 CFR 189.5 and 700.27

OMB Control Number 0910-0623—
Extension

FDA’s regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) set forth bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA-regulated human food and cosmetics. The regulations designate certain materials from cattle as “prohibited cattle materials,” including specified risk materials (SRMs), the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS) beef.

Sections 189.5(c) and 700.27(c) set forth the requirements for recordkeeping and records access for FDA-regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived from cattle. We issued these recordkeeping regulations under the adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), (a)(5), 601(c), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)). Under section 701(a) of the FD&C Act, we are authorized to issue regulations for the FD&C Act’s efficient enforcement. With regard to records concerning imported human food and cosmetics, we relied on our authority under sections 701(b) and 801(a) of the FD&C Act (21 U.S.C. 371(b) and 381(a)). Section 801(a) of the FD&C Act provides requirements with regard to imported human food and cosmetics and provides for refusal of admission of human food and cosmetics that appear to be adulterated into the United States. Section 701(b) of the FD&C Act authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act.

These requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know the following: (1) Whether cattle material may contain SRMs (brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the

transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia from animals 30 months and older and tonsils and distal ileum of the small intestine from all animals of all ages); (2) whether the source animal for cattle material was inspected and passed; (3) whether the source animal for cattle material was nonambulatory disabled, or MS beef; and (4) whether tallow in human food or cosmetics contain less than 0.15 percent insoluble impurities.

FDA’s regulations in §§ 189.5(c) and 700.27(c) require manufacturers and processors of human food and cosmetics manufactured from, processed with, or otherwise containing material from cattle establish and maintain records sufficient to demonstrate that the human food or cosmetics are not manufactured from, processed with, or otherwise contain prohibited cattle materials. These records must be retained for 2 years at the manufacturing or processing establishment or at a reasonably accessible location. Maintenance of electronic records is acceptable, and electronic records are considered to be reasonably accessible if they are accessible from an onsite location. Records required by these sections and existing records relevant to compliance with these sections must be available to FDA for inspection and copying. Existing records may be used if they contain all of the required information and are retained for the required time period.

Because we do not easily have access to records maintained at foreign establishments, FDA regulations in §§ 189.5(c)(6) and 700.27(c)(6), respectively, require that when filing for entry with U.S. Customs and Border Protection, the importer of record of human food or cosmetics manufactured from, processed with, or otherwise containing, cattle material must affirm that the human food or cosmetics were manufactured from, processed with, or otherwise contains, cattle material and must affirm that the human food or cosmetics were manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. In addition, if human food or cosmetics were manufactured from, processed with, or otherwise contains cattle material, the importer of record must provide within 5 business days records sufficient to demonstrate that the human food or cosmetics were not manufactured from, processed with, or otherwise contains prohibited cattle material, if requested.

Under FDA’s regulations, we may designate a country from which cattle materials inspected and passed for

human consumption are not considered prohibited cattle materials, and their use does not render human food or cosmetics adulterated. Sections 189.5(e) and 700.27(e) provide that a country seeking to be designated must send a written request to the Director of the Center for Food Safety and Applied Nutrition. The information the country is required to submit includes information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether SRMs, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, or MS beef from the country seeking designation should be considered prohibited cattle materials. We use the information to determine whether to grant a request for

designation and to impose conditions if a request is granted.

Sections 189.5 and 700.27 further state that countries designated under §§ 189.5(e) and 700.27(e) will be subject to future review by FDA to determine whether their designations remain appropriate. As part of this process, we may ask designated countries to confirm that their BSE situation and the information submitted by them, in support of their original application, has remained unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to periodic FDA 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 manufacturers, processors, and importers of FDA-

regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived from cattle, as well as, with regard to §§ 189.5(e) and 700.27(e), foreign governments seeking designation under those regulations.

In the **Federal Register** of August 14, 2020 (85 FR 49657), we published a 60-day notice requesting public comment on the proposed collection of information. Although some comments were received, only one pertained to the information collection. The comment suggested requiring greater than a 2-year retention period for records; however, we believe that additional retention requirements may impose undue burden on respondents to the information collection without providing greater utility to the Agency.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
189.5(c)(6) and 700.27(c)(6); affirmation of compliance.	54,825	1	54,825	0.033 (2 minutes)	1,809
189.5(e) and 700.27(e); request for designation	1	1	1	80	80
189.5(e) and 700.27(e); response to request for review by FDA.	1	1	1	26	26
Total	1,915

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Domestic facilities	697	52	36,244	0.25 (15 minutes)	9,061
Foreign facilities	916	52	47,632	0.25 (15 minutes)	11,908
Total	20,969

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: November 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Termination of the Food and Drug Administration's Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: The Department of Health and Human Services is issuing this Notice to withdraw FDA's Marketed Unapproved Drugs—Compliance Policy Guide, Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs, and to request information from the public regarding drugs that may be grandfathered or generally recognized as safe and effective.

DATES: Part I of this Notice shall be effective thirty days from the date of publication in the **Federal Register**. To be considered, responses and comments related to Part II of this Notice must be received electronically at the email