



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0505]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 information collection provisions of existing FDA regulations concerning FDA-regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived from cattle.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2009-N-0505 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 Division of Dockets Management. 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:

<http://www.gpo.gov/fdsys/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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), 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.

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. The FDA 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 (the 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, the FDA is authorized to issue regulations for the FD&C Act's efficient enforcement. With regard to records concerning imported human food and cosmetics, the FDA relied on its 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 contains 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 FDA does 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 containing-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 containing 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, FDA 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 (CFSAN Director). 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. FDA uses 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, FDA may ask designated countries to confirm their BSE situation and the information submitted by them, in support of their original application, has remained unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate. Therefore, designated countries may respond to periodic FDA requests by submitting information to confirm their designations remain appropriate. FDA uses 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.

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

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	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)	54,825	1	54,825	.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

Activity	Number of Recordkeepers	Number of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeper	Total Hours
Domestic facilities	697	52	36,244	.25 (15 minutes)	9,061
Foreign facilities	916	52	47,632	.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.

Except where otherwise noted, this estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled, "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle" published in the Federal Register of October 11, 2006 (71 FR 59653).

Reporting: FDA's regulations in §§ 189.5(c)(6) and 700.27(c)(6) impose a reporting burden on importers of human food and cosmetics manufactured from, processed with, or otherwise containing cattle material. Importers of these products must affirm that the human food or cosmetics are not manufactured from, processed with, or otherwise contain prohibited cattle materials and must affirm that the human food or cosmetics were manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. The affirmation is made by the importer of record to the FDA through FDA's Operational and Administrative System for Import Support. Affirmation by importers is expected to take approximately 2 minutes per entry line. Table 2 shows 54,825 lines of human food and cosmetics likely to contain cattle materials are imported annually. The reporting burden of affirming whether import entry lines contain cattle-derived materials is estimated to take 1,809 hours annually (54,825 lines × 2 minutes per line).

FDA's estimate of the reporting burden for designation under §§ 189.5 and 700.27 is based on its experience and the average number of requests for designation received in the past 3 years. In the last 3 years, FDA has not received any requests for designation. Thus, FDA

estimates that one or fewer will be received annually in the future. Based on this experience, FDA estimates the annual number of new requests for designation will be one. FDA estimates that preparing the information required by §§ 189.5 and 700.27 and submitting it to FDA in the form of a written request to the CFSAN Director will require a burden of approximately 80 hours per request. Thus, the burden for new requests for designation is estimated to be 80 hours annually, as shown in table 1, row 2.

Under §§ 189.5(e) and 700.27(e), designated countries are subject to future review by FDA and may respond to periodic FDA requests by submitting information to confirm their designations remain appropriate. In the last 3 years, FDA has not requested any reviews. Thus, FDA estimates that one or fewer will occur annually in the future. FDA estimates that the designated country undergoing a review in the future will need one-third of the time it took preparing its request for designation to respond to FDA's request for review, or 26 hours ($80 \text{ hours} \times 0.33 = 26.4 \text{ hours}$, rounded to 26). The annual burden for reviews is estimated to be 26 hours, as shown in table 1, row 3. The total reporting burden for this information collection is estimated to be 1,915 hours annually.

Recordkeeping: FDA estimates that there are 697 domestic facility relationships and 916 foreign facility relationships consisting of the following facilities: An input supplier of cattle-derived materials that requires records (the upstream facility) and a purchaser of cattle-derived materials requiring documentation (this may be a human food or cosmetics manufacturer or processor). The recordkeeping burden of FDA's regulations in §§ 189.5(c) and 700.27(c) is the burden of sending, verifying, and storing documents regarding shipments of cattle material that is to be used in human food and cosmetics.

In this estimate of the recordkeeping burden, FDA treats these recordkeeping activities as shared activities between the upstream and downstream facilities. It is in the best interests of both facilities in the relationship to share the burden necessary to comply with the regulations; therefore, FDA estimates the time burden of developing these records as a joint task between the two facilities. Thus, FDA estimates that this recordkeeping burden will be about 15 minutes per week, or 13 hours per year, and FDA assumes that the recordkeeping burden will be shared between 2 entities (i.e., the ingredient supplier and the manufacturer of finished products). Therefore, the total recordkeeping burden for domestic facilities is estimated to be 9,061 hours (13 hours \times 697), and the total recordkeeping burden for foreign facilities is estimated to be 11,908 hours (13 hours \times 916), as shown in table 2.

Dated: June 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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