DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0505]

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 (PRA).

DATES: Submit either electronic or written comments on the collection of information by October 27, 2014.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0623. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

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)—Revision

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. FDA issued these recordkeeping regulations under the adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), and (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), and (a)(5), 361(c), and 371(a)). Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the FD&C Act's efficient enforcement. With regard to records concerning imported human food and cosmetics, 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 (SRMs include 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 less than 30 months old 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 a human food or cosmetics contain less than 0.15 percent insoluble impurities.

FDA's regulations in §§ 189.5(c) and 700.27(c) require that 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 containing 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 contain 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 are manufactured from, processed with, or otherwise containing cattle material, the importer of record must, if requested, provide within 5 business days records sufficient to demonstrate that the human food or cosmetics are not manufactured from, processed with, or otherwise containing prohibited cattle material.

Upon review of the information collection requests supporting these BSE-related regulations, FDA found that the burdens associated with the requirements for recordkeeping and records access found in §§ 189.5(c) and 700.27(c) are in use without current OMB approval. This collection of information was previously approved by OMB under control number 0910–0597. FDA submitted a timely information collection request to extend the approval of 0910–0597, but the request was denied. To most appropriately streamline this information collection and to eliminate redundancy in information collection requests, FDA seeks to revise the 0910–0623 collection to include the reporting and

recordkeeping elements of 0910–0597. FDA has included these elements in the burden estimates and discussion in this document.

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 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 whether 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 that their BSE situations 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 that their designations remain appropriate. FDA uses the information to ensure the 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 1, 2014 (79 FR 44785), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it did not respond to the four collection of information topics solicited, and therefore, it will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

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 BURDEN[1]

21 CFR §§ 189.5(c) and 700.27(c)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	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.

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 at 59667).

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 containing 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 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 of this document 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 multiplied by 0.033 (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 1 of this document.

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 hours multiplied by 0.33 (2 minutes) = 26.4 hours, rounded to 26). The annual burden for reviews is estimated to be 26 hours, as shown in table 1, row 2 of this document. The total annual reporting burden for this information collection is estimated to be 1,915 hours.

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 multiplied by 697), and the total recordkeeping burden for foreign facilities is estimated to be 11,908 hours (13 hours multiplied by 916), as shown in table 1 of this document.

Dated: September 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1242]

Submissions for Early Growth Response 1 Gene Fluorescence In-Situ Hybridization Test System for Specimen Characterization Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices.'' This draft guidance provides industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 26, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Shyam Kalavar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5568, Silver Spring, MD 20993–0002, 301–796–6807.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document was developed to provide industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization devices and recommendations for addressing certain labeling issues relevant to the review process specific to these devices. An early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization is a device intended to detect the EGR1 probe target on chromosome 5q in bone marrow specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted only by a qualified pathologist or cytogeneticist. These devices do not include automated systems that directly report results without review and interpretation by a qualified pathologist or cytogeneticist. These devices also do not include any device intended for use to select patient therapy, predict patient response to therapy, or to screen for disease as well as any device with a claim for a