applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained electronically in the CCIIO developed database for collection, tracking and storage of casework information and for reporting purposes. Any manually maintained records will be kept in locked cabinets or otherwise secured areas.

RETRIEVABILITY:

The records are retrieved electronically by a variety of fields, including but not limited to name, State, zip code, and health insurance identification number issued to the individual.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 10 years. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER(S) AND ADDRESS:

Team Lead, Health Insurance Assistance Team, Office of Consumer Support, Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name and the retrieval selection criteria (*e.g.,* name, health insurance claim number, SSN, *etc.*).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

The identifying information contained in these records is provided voluntarily by the individual consumers, confidential informants, or by reports received from other sources . Additional case-relevant information may also be provided by the individual's employer or insurer to assist in achieving resolution of the specific case.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2011–9105 Filed 4–14–11; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0264]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Designation as Country Not Subject to the Restrictions Applicable to 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 regarding countries seeking to be designated as not subject to certain bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA-regulated human food and cosmetics.

DATES: Submit either electronic or written comments on the collection of information by June 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Request for Designation as Country Not Subject to the Restrictions Applicable to 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)

Section 801(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(a)) provides requirements with regard to imported food and cosmetics and provides for refusal of admission into the United States of human food and cosmetics that appear to be adulterated. Section 701(b) of the FD&C Act (21 U.S.C. 371(b)) 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. To address the potential risk of BSE in human food and cosmetics, FDA regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) designate certain materials from cattle as "prohibited cattle materials," including specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS) (Beef). Under the regulations no human food or cosmetic may be manufactured from, processed with, or otherwise contain prohibited cattle materials. However, the Agency 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 a human food or cosmetic adulterated.

Sections 189.5(e) and 700.27(e) provide that a country seeking to be so designated must send a written request to the Director, Center for Food Safety and Applied Nutrition (CFSAN). 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 specified risk materials, 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 that have been designated under §§ 189.5(e) and 700.27(e) will be subject to future review by FDA to determine whether designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate. Therefore, designated countries may respond to periodic requests by FDA by submitting information to confirm that their designation remains appropriate. FDA uses the information to ensure that their designation remains appropriate.

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 and 700.27— 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					106

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

This estimate is based on FDA's experience and the average number of requests for designation under §§ 189.5 and 700.27 received in the past 3 years. FDA received one request for designation in 2009 and one in 2010. Based on this experience, FDA estimates the annual number of new requests for designation will be 1. FDA estimates that preparing the information required by §§ 189.5 and 700.27 and submitting it to the Agency in the form of a written request to the Director, CFSAN will require a burden of approximately 80 hours per request. Thus, the annual burden for new requests for designation is estimated to be 80 hours, 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 requests by FDA by submitting information to confirm that their designation remains appropriate. In the last 3 years, FDA has not requested any reviews. Thus, the Agency estimates that one or fewer will occur annually in the future. We estimate that the designated country undergoing a review in the future will need one third the time it took preparing its request for designation to respond to FDA's request for review, or 26 hours (80 hours x 0.33 = 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 burden for this information collection is estimated to be 106 hours.

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9154 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0263]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak

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