United States Food and Drug Administration
Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material from Cattle

OMB Control No. 0910-0623

SUPPORTING STATEMENT: Part A - Justification

1. Circumstances Making the Collection of Information Necessary

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), (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, FDA is authorized to issue regulations for the FD&C Act's efficient enforcement. Regarding 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 human food or cosmetics contain less than 0.15 percent insoluble impurities.

FDA is therefore requesting OMB approval of the following information collection provisions:

21 CFR 189.5(c), 700.27(c) – Recordkeeping
FDA's regulations in §§ 189.5(c) and 700.27(c) require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain,

material from cattle establish and maintain records sufficient to demonstrate that the human food or cosmetic is not manufactured from, processed with, or does not 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.

21 CFR 189.5(c)(6), 700.27(c)(6) -- Reporting
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 a human food or cosmetic manufactured from, processed with, or otherwise containing, cattle material must affirm that the human food or cosmetic was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the human food or cosmetic was manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. In addition, if a human food or cosmetic is manufactured from, processed with, or otherwise contains, cattle material, then the importer of record must, if requested, provide within 5 business days records sufficient to demonstrate that the human food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material.

21 CFR 189.5(e), 700.27(e) -- Reporting
Request for designation -- Requires that countries seeking to be designated under §§ 189.5(e) and 700.27(e) send a written request to the Director, Center for Food Safety and Applied Nutrition (CFSAN).

21 CFR 189.5(e), 700.27(e) -- Reporting
Response to request for review -- Requires that countries that have been designated under §§ 189.5(e) and 700.27(e) respond to periodic requests by FDA.

2. Purpose and Use of the Information Collection

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 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 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 containing prohibited cattle material, if requested.

As noted above, §§ 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.

As noted above, §§ 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.

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.

3. Use of Improved Information Technology and Burden Reduction

Sections 189.5(c) and 700.27(c) do not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in their recordkeeping. Records on bovine materials and ingredients subject to the regulations may be kept in paper or electronic form, as long as they are easily accessible by FDA should the need arise. As noted above, maintenance of electronic records is acceptable and electronic records are considered to be reasonably accessible if they are accessible from an

onsite location. For §§ 189.5(e) and 700.27(e), FDA receives entries made to CBP's ACE system electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative reporting or recordkeeping requirements. FDA and the U.S. Department of Agriculture (USDA) agencies, the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS), have different regulatory responsibilities with respect to preventing BSE and ensuring food safety. FDA consults with APHIS and FSIS as part of its evaluation process. Further, FDA takes into consideration available risk assessments of other competent authorities in conducting its evaluation. Though it is not required, a previous BSE evaluation by USDA, or by another country or another competent authority, will be helpful to FDA in its review and may decrease the time needed for FDA to make a determination.

5. Impact on Small Businesses or Other Small Entities

For §§ 189.5(c) and 700.27(c), FDA estimates that approximately ten percent (10%) of the respondents are small businesses. The regulations do not significantly impact small businesses as the records FDA suggests that manufacturers and processors keep are typically already kept by businesses for tax and other purposes. The same information is requested from large and small firms and is the minimal amount needed. There is no special burden placed on small businesses by these information collection provisions. The reporting and recordkeeping provisions are applicable to all businesses including small businesses. However, FDA aids small businesses in dealing with the requirements of the FD&C Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. For §§ 189.5(e) and 700.27(e), none of the respondents are small businesses; they are foreign governments.

6. Consequences of Collecting the Information Less Frequently

FDA requires that records on each shipment of bovine ingredients used in food, dietary supplement, and cosmetic production be kept for two years. Information is necessary on each shipment of bovine materials to verify that source animals were under 30 months of age, were ambulatory, and passed USDA inspection. There is no apparent way to minimize the burden of collecting this information on each shipment.

Frequency of recordkeeping varies for different processors. FDA does not "collect" these records as a routine matter. Records are maintained on file at each processing facility and will be examined there periodically by the FDA.

Delayed or less frequent recordkeeping or reporting would lessen the effectiveness of the regulations to prevent use of prohibited cattle materials in human food and cosmetics. There is currently no validated ante-mortem test to reliably detect the presence of the BSE agent or the presence of prohibited cattle material in human food and cosmetics. Once cattle material such as brain or spinal cord is separated from the source animal, it may not be possible to determine the

age of the animal from which the material came without records and, therefore, whether the material is specified risk material. In addition, without records, it may not be possible to determine whether a product contains material from cattle that were not inspected and passed for human consumption. Also, a product might contain MS beef without its presence being evident from the appearance of the product.

Because there is currently no way to test reliably for the presence of the BSE agent or for the presence of prohibited cattle materials, manufacturers and processors of human food and cosmetics must depend on records from their suppliers of cattle materials to ensure that their source material does not contain prohibited cattle materials. Without records documenting the absence of prohibited cattle materials in source materials, manufacturers and processors of human food and cosmetics cannot know whether they are adulterating their products by including prohibited cattle materials. Therefore, a failure of manufacturers and processors to establish and maintain such records results in human food and cosmetics being prepared under insanitary conditions whereby they may have been rendered injurious to health. Furthermore, without adequate records, FDA cannot know whether manufacturers and processors of human food have complied with the prohibitions against use of prohibited cattle materials. Therefore, the recordkeeping requirements are necessary for the efficient enforcement of the IFR. Failure to comply with the recordkeeping requirements would render the affected human food and cosmetics adulterated under sections 402(a)(4) and 601(a) of the FD&C Act, respectively.

Data collection occurs occasionally for §§ 189.5(e) and 700.27(e). Only those countries seeking the designation provided for in §§ 189.5(e) and 700.27(e) will submit information to FDA. If the collection is not conducted, the designation will not be available to interested countries.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of June 15, 2017 (82 FR 27501), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments. One comment was unrelated to the information collection; one comment noted that the length of time to keep records was insufficient but suggested no alternative timeframe; and one comment supported the information collection. After evaluating these comments FDA did not revise the information collection.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Company records may be consulted during FDA plant inspections. Records that the agency may copy or take possession of will be treated as records that are exempt from release under the provisions of the Freedom of Information Act (FOIA) to the maximum extent permitted by that statute and FDA regulations. Confidential commercial information is protected from disclosure under FOIA under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1. --Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. 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 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					1,915

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

Except where otherwise noted, this estimate retains the estimated number of facilities identified in 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 at CBP entry. Affirmation by importers is expected to take approximately 2 minutes per entry line.

Table 1 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 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 hours × 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 3. The total reporting burden for this information collection is estimated to be 1,915 hours annually.

Table 2. --Estimated Annual Recordkeeping Burden[1]

21 CFR §§189.5(c) and 700.27(c)	No. of Recordkeepers	No. 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 or operating and maintenance costs associated with this collection of information.

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 2.

12 b. Annualized Cost Burden Estimate

FDA estimates the hour burden costs to respondents choosing to submit a request for designation to be $8,588.80. FDA estimates that the average hourly wage for the employee preparing and submitting the request for designation would be equivalent to a GS-14/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017, approximately $53.68/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $107.36/hour. Thus, the overall estimated cost incurred by the respondents is $8,588.80 (80 burden hours x $107.36/hr = $8,588.80).

FDA estimates the hour burden costs to countries that respond to requests for review by FDA to be $2,791.36. FDA estimates that the average hourly wage for the employee preparing the response would be equivalent to a GS-14/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017, approximately $53.68/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $107.36/hour. Thus, the overall estimated cost incurred by the respondents is $2,791.36 (26 burden hours x $107.36/hr = $2,791.36).

FDA estimates the recordkeeping and reporting hour burden costs to be approximately $2,445,446.08 (Table 1, row 1 and Table 2). This estimate is based upon an employee making a salary equivalent to a GS-14/Step 1 rate for the Washington-Baltimore locality pay area for the year 2017, approximately $53.68/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $107.36/hour. Thus, the overall estimated cost incurred by the respondents is $2,445,446.08 (22,778 burden hours x $107.36/hour = $2,445,446.08).

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Submitting a request for designation	80	$107.36	$8,147.20
Responding to FDA requests for review	26	$107.36	$2,647.84
Recordkeeping and reporting costs from Table 1, row 1 and Table 2	22,778	$107.36	$2,445,446.08
Total			$2,456,241.12

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

It takes FDA approximately 80 hours to review a request for designation. FDA estimates the hourly cost for review and evaluation is $53.68/hour, the GS-14/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017. Doubling this wage to account for overhead costs, we calculate the hourly cost is $107.36/hour. Thus, the cost to the Federal government is estimated to be $8,588.80 per review (80 hours x $107.36/hour = $8,588.80). Estimating one request for designation will be submitted to us annually, the total annualized cost for reviewing a request for designation is $8,588.80.

It takes FDA approximately 26 hours to review a successful designation. FDA estimates the hourly cost for this review is $53.68/hour, the GS-14/Step-1 rate for the Washington- Baltimore locality pay area for the year 2017. Doubling this wage to account for overhead costs, we calculate the average hourly cost is $107.36/hour, for a total cost of $2,791.36 per review (26 hours x $107.36/hour = $2,791.36). Assuming one successful designation occurs annually, the total annualized cost is $2,791.36.

Thus, the combined total annualized cost to the Federal government for BSE designation and review is $11,380.16 ($8,588.80 [review request for designation]) + ($2,791.36 [review successful designation]).

FDA's review of retained records generally occurs as part of our routine or *for-cause* establishment inspection activities, where we devote approximately 5 hours to the inspection of records. We estimate the annualized cost for the review of records retained by a firm to be $430.90 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation to be $45.42 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017. Five hours multiplied by $45.42 per hour equals $227.10. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government $454.20 per review. There are approximately 697 domestic facilities. If each is inspected annually, we estimate a total annual cost of $316,577.40.

15. Explanation for Program Changes or Adjustments

The estimated burden for the information collection is unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

We are not publishing any information received as a result of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.