Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured from, Processed With, or Otherwise Containing, Material from Cattle

OMB No. 0910-0597

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Sections 189.5(c) and 700.27(c) (21 CFR 189.5(c) and 700.27(c)) of FDA's regulations set forth the requirements for recordkeeping and records access for FDA-regulated human food, including dietary supplements, and cosmetics that are manufactured from, processed with, or otherwise contain, 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 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 act, FDA is authorized to issue regulations for the act's efficient enforcement. With regard to records concerning imported human food and cosmetics, FDA relied on its authority under sections 801(a) and 701(b) of the act (21 U.S.C. 381(a) and 371(b)). Section 801(a) of the act 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 act authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the 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 specified risk materials (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 cattle 30 months and older and tonsils and distal ileum of the small intestine from cattle of all ages; (2) whether the cattle material came from cattle not inspected and passed; (3) whether the cattle material came from cattle that were nonambulatory disabled; (4) whether the material consists of mechanically separated beef; and (5) whether tallow in a human food or cosmetic contains less than 0.15 percent insoluble impurities.

These regulations, published on October 11, 2006 in the final rule entitled, "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From Processed With, Otherwise Containing Material From Cattle" (71 FR 59653), implement recordkeeping for the provisions of FDA's interim final rule entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics'' (the IFR) (69 FR 42256, July 14, 2004).

FDA is 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.

2. Purpose and Use of the Information Collection

The records required by §§ 189.5(c) and 700.27(c) are compiled and maintained by manufacturers and processors of human food and cosmetics. The information collected is used by these processors to ensure their products do not contain prohibited cattle materials. The information collected also is used by FDA to ensure compliance with the provisions of the IFR.

Description of Respondents: Respondents to this information collection include manufacturers, processors, and importers of FDA regulated human food, including dietary supplements, and cosmetics that are manufactured from, processed with, or otherwise contain, material derived from cattle. Respondents are from the private sector (for profit businesses).

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.

FDA estimates that ninety-five percent (95%) of the recordkeepers will use electronic means to keep the required records.

Sections 189.5(c)(6) and 700.27(c)(6) specify 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.

FDA estimates that one hundred percent (100%) of the respondents will use electronic means to submit the required affirmation when filing for entry with U.S. Customs and Border Protection.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of recordkeeping requirements as a result of FDA's regulation for food and cosmetics and the the U.S. Department of Agriculture (USDA) BSE regulations covering meat and meat products (72 FR 38699; July 13, 2007). Both the FDA and USDA regulations declare specified risk materials and the carcasses and parts of nonambulatory disabled cattle to be inedible, unfit for human food, and prohibit their use as human food, and require that tonsils and the distal ileum of the small intestine be removed and disposed of as inedible. USDA requires records on some of the meat products that they regulate. FDA is requiring records on the meat-based products that it regulates.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that approximately ten percent (10%) of the respondents are small businesses. This rule does 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 act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency.

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 act, respectively.

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 accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of October 23, 2009 (74 FR 54827). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift 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, the 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 any 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 of this collection of information as follows:

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).

Recordkeeping

Table 1.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
Domestic Facilities 189.5(c) and 700.27(c)	697	52	36,244	15/60	9,061
Foreign Facilities 189.5(c) and 700.27(c)	916	52	47,632	15/60	11,908
Total					20,969

FDA estimates that there are 697 domestic facility relationships (71 FR at 59667), and 916 foreign facility relationships (71 FR at 59663), 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 cosmetic 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, we treat 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, we estimate the time burden of developing these records as a joint task between the two facilities. Thus, we estimate that this recordkeeping burden will be about 15 minutes per week, or 13 hours per year (71 FR at 59667), and we assume that the recordkeeping burden will be shared between two entities (*i.e.*, the ingredient supplier and the manufacturer of finished products). Therefore, the total recordkeeping burden for domestic facilities is estimated to be 13 hours × 697 = 9,061 hours, and the total recordkeeping burden for foreign facilities is estimated to be 13 hours × 916 = 11,908 hours, as shown in table 1 of this document. FDA bases its estimate of the hours per response on its experience with similar recordkeeping requirements.

Reporting

Table 2.--Estimated Annual Reporting Burden					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
189.5(c)(6) and 700.27(c)(6)	54,825	1	54,825	2/60	1,809

FDA's regulations in §§ 189.5(c)(6) and 700.27(c)(6) impose a reporting burden on importers of human food and cosmetics that are manufactured from, processed with, or otherwise contain, cattle material. Importers of these products must affirm that the food or cosmetic is manufactured from, processed with, or does not otherwise contain, prohibited cattle materials and must affirm that the human food or cosmetic was 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 the agency's Operational and Administrative System for Import Support (OASIS). Affirmation by importers is expected to take approximately 2 minutes per entry line. Table 2 of this document shows that 54,825 lines of food and cosmetics that likely contain cattle materials are imported annually (71 FR at 59667). The annual 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 bases its estimate of the hours per response on its experience with similar reporting requirements.

12 b. Annualized Cost Burden Estimate

FDA estimates the total recordkeeping and reporting hour burden costs to be approximately $ 1,681,699.74. This estimate is based upon the an employee making a salary equivalent to a GS-14-1 level in the locality pay area of Washington-Baltimore in 2009, $49.22/hour, increased to $73.83 to account for overhead. Thus we estimate $73.83 per hour x 22,778 hours = $1,681,699.74.

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 information collection.

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its routine or for cause establishment inspection activities. FDA would devote approximately 5 hours per inspection to the inspection of records. FDA estimates the annualized cost to the Federal Government for the review of records retained by a firm to be $426.60 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation to be $42.66 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2010. Five hours multiplied by $42.66 per hour equals $213.30. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal Government $426.60 per review. There are 697 domestic facilities. If each was inspected annually, FDA estimates that the total annual cost to the Federal Government would be $297,340.20, rounded to $297,340.

15. Explanation for Program Changes or Adjustments

As shown in tables 1 and 2 above, CFSAN has made adjustments in the burden estimates to correct errors in the recordkeeping burden and has added a reporting burden table for a reporting burden which was inadvertently submitted as recordkeeping burden. A more detailed explanation for these changes follows.

On October 11, 2006, FDA published in the Federal Register a final rule entitled, "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From Processed With, Otherwise Containing Material From Cattle." As per that final rule, we estimated four IC's, for a total of 43,039 hours:

IC#1: one time training and record design burdens - 30,898 hours
IC#2: weekly recordkeeping (15 mins/week) - 9,061 hours
IC#3: importer affirmation to FDA (2 mins/import) - 1,809 hours (in ICRAS as 21 hours)
IC#4: one time training and record design burdens - 3,059 hours

Unfortunately, IC#3 was erroneously estimated and submitted in ICRAS/ROCIS as recordkeeping burden, when it should have been submitted as reporting burden. There was an additional error in IC#3: IC#3 was submitted in ICRAS/ROCIS as an estimate of only 21 hours, instead of the 1,809 hours estimated in the supporting statement. Finally, IC#2, the weekly recordkeeping estimate included only the recordkeeping burden on domestic firms and failed to include the recordkeeping requirement on foreign firms. These errors were corrected in the 2010 submission.

In 2010, we estimated three IC's, for a total of 22,778 hours, as shown in tables 1 and 2 of this supporting statement. Two of these IC's contained burden estimates that remained the same as the 2006 estimates (see blue text):

IC#1: weekly recordkeeping DOMESTIC (15 mins/week) - 9,061 hours
IC#2: weekly recordkeeping FOREIGN (15 mins/week) - 11,908 hours
IC#3: reporting - importer affirmation to FDA (2 mins/import) - 1,809 hours

The changes in the 2010 estimates from the 2006 estimates can be described as follows. In 2010, we reported a reduction in total burden of 20,261 hours, from 43,039 hours to 22,778 hours (43,039 – 22,778 = 20,261). In 2010, we no longer included in our estimate the 33,957 hours associated with 2006's IC# 1 (30,898 hours) and IC #4 (3,059 hours) - the one-time training and record design burden hours associated with implementing the 2006 rule. This change led to a reduction of 33,957 hours (30,898 + 3,059 = 33,957 hours). In 2010, we reported a increase in burden of 1,788 hours when we corrected the 2006 error whereby 2006's IC#3 was submitted as 21 hours, instead of 1,809 hours. This change led to an increase of 1,788 hours (1,809 – 21 = 1,788 hours). Finally, in 2010, we reported a increase in burden of 11,908 hours when we corrected the 2006 error that failed to include the recordkeeping requirement on foreign firms. This change led to an increase of 11,908 hours. Thus, in summary, the reduction **(adjustment)** of 20,261 hours reflects the net effect of these changes
(-33,957 + 1,788 + 11,908 = -20, 261).

16. Plans for Tabulation and Publication and Project Time Schedule

FDA has no plans to publish data from this information collection.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.