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

SUPPORTING STATEMENT

A. Justification

1. Circumstances Necessitating Information Collection

On July 14, 2004, the Food and Drug Administration (FDA, we) published an interim final rule (IFR) entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics" (69 FR 42255). FDA issued the IFR to prohibit the use of certain cattle material to address the potential risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the 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 of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. FDA took this action in response to the finding of an adult cow, imported from Canada, that tested positive for BSE in the State of Washington. The IFR will minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

In a 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, FDA is requiring 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 that document the absence of prohibited cattle materials in such products and require that such records be made available to FDA for inspection and copying. FDA is requiring recordkeeping because records are necessary to help FDA ensure compliance with the requirements of the interim final rule, and manufacturers and processors of human food and cosmetics need records to ensure their products do not contain prohibited cattle materials.

FDA issued this recordkeeping final rule under the adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), (a)(5), 601(c), and under section 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)) (Attachment 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 (Attachment 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.

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

21 CFR 189.5(c), 700.27(c)

In §§ 189.5(c) and 700.27(c), we are requiring 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 two 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.

21 CFR 189.5(c)(6), 700.27(c)(6)

Because we do not easily have access to records maintained at foreign establishments, we are requiring in §§ 189.5(c)(6) and 700.27(c)(6), respectively, 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 is manufactured from, processed with, or otherwise contains, cattle material and must affirm that the human food or cosmetic was manufactured in accordance with the recordkeeping rule. 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 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. How, By Whom, Purpose of Collection

The records required by this rule are compiled and maintained by manufacturers and processors of human food and cosmetics. The information to be collected will be used by these processors to ensure their products do not contain prohibited cattle materials. The information to be collected will also be used by FDA to ensure compliance with the provisions of the IFR.

There is currently no validated premortem 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 proposed recordkeeping requirements are necessary for the efficient enforcement of the interim final rule. 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.

FDA recommends that manufacturers and processors maintain records, which they renew at least annually, from suppliers of cattle materials and of products that are manufactured from, processed with, or otherwise contain cattle material documenting that the products obtained from the supplier do not contain prohibited cattle materials. In addition, we recommend that manufacturers and processors maintain a record of the source, type, volume, and date of receipt for cattle material or product manufactured from, processed with, or otherwise containing cattle material.

Importers of products that use bovine ingredients will be asked by U.S. Customs and Border Protection to affirm the use of cattle materials in FDA-regulated food products. If requested by FDA, importers of foods that contain bovine materials must provide records within 5 days sufficient to support the affirmation (i.e., to demonstrate that the human food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material). The importer of record must retain or have access to the same records that domestic manufacturers and processors must maintain to demonstrate compliance.

3. Consideration Given to Information Technology

This regulation does 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 this final rule 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.

4. Identification of Duplicative Information

This is a new information collection. There is no duplication of recordkeeping requirements as a result of FDA's regulation and the interim final rule issued by the U.S. Department of Agriculture (USDA) declaring specified risk materials and the carcasses and parts of nonambulatory disabled cattle to be inedible, unfit for human food, and prohibiting their use as human food and requiring that the entire 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 we regulate. In addition, the FDA IFR is consistent with the interim final rule issued by the USDA.

5. Small Businesses

This rule is not expected to 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.

6. Less Frequent Information Collection

FDA will require 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 will vary for different processors. FDA will not "collect" these records as a routine matter. Records will be maintained on file at each processing facility and will be examined there periodically by the FDA.

7. Special Circumstances

The collection of information does not involve submission of information to the agency, written responses to the agency, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA, or require the disclosure of trade secrets or other confidential information.

8. Consultations with Persons Outside the FDA

FDA published a proposed rule on July 14, 2004 in the Federal Register (69 FR 42275). There were no comments to the proposal that specifically addressed paperwork reduction issues.

9. Payment or Gift

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality Provisions

Company records which may be consulted during FDA plant inspections are subject to FDA's regulations on the release of information, 21 CFR Part 20. 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 to the maximum extent permitted by that statute and FDA regulations.

11. Privacy

This information collection does not involve any questions of a sensitive nature.

12. Burden of Information Collection

FDA estimates the burden for this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Capital Costs	Total Hours
189.5(c) and 700.27(c)	697	1	697	44.33	$480,930	30,898
189.5(c) and 700.27(c)	697	52	36,244	0.25	$0	9,061
189.5(c)(6) and 700.27(c)(6)	54,825	1	54,825	0.033	$0	1,809
189.5(c) and 700.27(c)	69.7	1	69.7	44.33	$48,093	3,090
Total one time burden hours						30,898
Total recurring burden hours						13,960

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

Burden:

Hour Burden Estimate

FDA has determined that there are 697 domestic facility relationships, consisting of the following facilities: An input supplier of cattle-derived materials that require records (the upstream facility) and a purchaser of cattle-derived materials requiring documentation--this may be a human food or cosmetic manufacturer or processor. Together, the upstream

and downstream facilities are responsible for designing records, verifying records, and storing records that contain information on sources of cattle materials.

In this hour burden estimate, as in the economic analysis, 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 this final rule; therefore we estimate the time burden of developing these records as a joint task between the two facilities.

One Time Burden

The one-time burden of the final recordkeeping requirement consists of the facilities training their employees on how to keep the records necessary to comply with this rule and designing the records. The one-time training burden incurred for each facility is assumed to be approximately one-third of an hour. This time includes both the training required for personnel to verify that appropriate records have been received or created, and also the training required by personnel to file and maintain those records. Therefore, the total one-time training burden is 697 x 0.33 hrs = 230 hours.

We use the FDA Labeling Cost Model to estimate the one-time records design costs per facility of $1,785. This cost includes the costs of designing records for multiple products and consists of $1,095 in labor costs (and $690 in capital costs which we deal with in the next section of this document). Dividing the $1,095 of labor costs by the hourly wage for workers of $25.10 (doubled to include overhead), we have a design-time burden per facility of about 44 hours; we multiplied the burden per facility by 697 facilities to get an estimated total training and design burden of 30,668 hours.

Row 1 of table 1 shows the total hour burden from training and records design to be 44.33 hours per facility x 697 recordkeepers = 30,898 hours for the year.

Recurring Burden

The recurring recordkeeping burden is the burden of sending and verifying documents regarding shipments of cattle material that is to be used in human food and cosmetics. We estimate that this recurring recordkeeping burden will be about 15 minutes per week, or 13 hours per year. FDA assumes that this recordkeeping burden will be shared between two entities (i.e., the ingredient supplier and the manufacturer of finished products). Therefore the total recurring burden will be 13 hours x 697 = 9,061 hours, as shown in row 2 of table 1.

There will also be a recurring recordkeeping burden for 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 not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. Affirmation by importers is expected to take approximately 2 minutes per

entry line. Row 3 of table 1 shows that 54,825 lines of food and cosmetics that likely contain cattle materials are imported annually. This total represents 10 percent of the total lines imported for fiscal year 2004 for products under FDA product codes that FDA will be looking to for importer affirmation. 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 x 2 minutes per line).

In addition, there will be an annual burden associated with new firms entering the industry. As in the analysis of the Bioterrorism Act recordkeeping rule, we assume that the average annual rate of turnover is 10 percent. We therefore estimate (row 4 of table 1) the annual one-time burden for new firms entering the industry to be 10 percent of the one-time burden of existing firms estimated.

13. Total Annual Cost

We use the FDA Labeling Cost Model to estimate the one-time record design costs per facility of $1,875 per facility, based on the facility producing multiple products with ingredients that now require records. Over $1,000 of the record design cost is due to labor, but $690 of the records design represents capital costs to each facility. The total capital costs for records design for all facilities is $690 x 697 = $480,930. These one time costs are shown in row 1 of table 1. We estimate the annual capital costs for new firms entering the industry to be 10 percent of the one-time burden of existing firms, or $48,093. These annual costs are shown in row 4 of table 1.

14. Annual Cost to Government

FDA estimates that the annualized cost to the Federal Government for the review of records in cases where compliance is questioned or when record review is necessary to help determine the location of bovine materials potentially contaminated with BSE will not significantly increase the current annual expenditures for ongoing facility inspections.

15. Reason for Change

This is a new collection.

16. Statistical Reporting

FDA has no plans for publication from this information collection.

17. Display of OMB Approval Date

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", of OMB Form 83I

No exception to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.