TAB C

Display Date 7-9-04 11:00am.
Publication Date 7-14-04
Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 189 and 700

[Docket No. 2004N–0257]

RIN 0910–AF48

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. This is a companion rulemaking to FDA's interim final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics," published in this issue of the **Federal Register.** FDA is proposing recordkeeping requirements because records documenting the absence of prohibited cattle materials are needed by manufacturers and processors of human food and cosmetics that contain cattle material to ensure that these products do not contain prohibited cattle materials. In addition, such records are necessary to help FDA ensure compliance with the requirements of the interim final rule.

cf0448

DATES: You may submit written or electronic comments on the proposed rule by [*insert date 30 days after date of publication in the* **Federal Register**]. Submit written comments on the information collection requirements by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0257, by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

• E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0257 in the subject line of your e-mail message.

• FAX: 301–827–6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Effective Date and Opportunity for Public Comment" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Rebecca J. Buckner, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1486.

SUPPLEMENTARY INFORMATION:

I. Background

In this issue of the **Federal Register** we are publishing an interim final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics" (referred to as the "interim final rule") to prohibit the use of prohibited cattle materials in human food, including dietary supplements, and cosmetics. Prohibited cattle materials include specified risk materials (SRMs), 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). SRMs 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. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. The preamble to the interim final rule describes the background and justification for the ban on prohibited cattle materials in human food and cosmetics.

In this companion rulemaking, we are proposing that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. We believe that records documenting the absence of prohibited cattle materials in human food and cosmetics are critical for manufacturers, processors, and FDA to ensure compliance with the ban on the use of prohibited cattle materials in the interim final rule. Once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is prohibited cattle material. There is currently no way to test reliably for the presence of the bovine spongiform encephalopathy (BSE) agent or for the presence of prohibited cattle materials. Therefore, manufacturers and processors of human food and cosmetics must depend on records from the suppliers of cattle material to demonstrate that the supplier's cattle material does not contain prohibited cattle materials.

Through these records, manufacturers and processors of human food and cosmetics can ensure that prohibited cattle materials are not included in their products. The agency believes that recordkeeping and records access

requirements are necessary immediately. The agency recognizes, however, that recordkeeping systems cannot be put into place immediately and, therefore, to include recordkeeping requirements in the interim final rule could result in manufacturers and processors immediately being in violation of the adulteration provisions of the Federal Food, Drug, and Cosmetic Act (the act) with respect to food and cosmetics because of their failure immediately to establish and maintain the necessary records as of the effective date of the interim final rule. For that reason, we are proposing record establishment and maintenance requirements in this separate rulemaking, rather than including them in the interim final rule. In addition, the agency is seeking information from the public regarding the types of records that may already be available to document the absence of prohibited cattle materials in human food and cosmetics and the types of records that could be established to document the absence of prohibited cattle materials in these FDA-regulated products. In the meantime, FDA is ensuring that it can enforce the new prohibitions in the interim final rule through the provisions in that rule requiring FDA be given access to any existing records relevant to compliance with the ban on prohibited cattle materials.

II. Definitions From the Interim Final Rule

The following definitions are from the interim final rule (new §§ 189.5(a) and 700.27(a) (21 CFR 189.5(a) and 700.27(a))) and are included here because they are relevant to the proposed recordkeeping provisions:

• *Prohibited cattle materials* means specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or MS(Beef). The phrase "prohibited cattle materials" includes all of the individual categories of materials and tissues

prohibited by this rulemaking. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.

• *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated. This definition is consistent with the U.S. Department of Agriculture's (USDA's) definition in 9 CFR 301.2.

• *Mechanically Separated (MS) (Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses, that meets the specifications contained in 9 CFR 319.5, the USDA regulation that prescribes the standard of identity for MS (Species). This definition of MS(Beef) is consistent with the term as used by USDA in its recent BSE interim final rule (January 12, 2004, 69 FR 1862) prohibiting its use in food.

• *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions. This definition of nonambulatory disabled cattle is consistent with the definition of nonambulatory disabled livestock in USDA's BSE interim final rule requiring nonambulatory disabled cattle be condemned and not used as human food.

• *Specified risk material (SRM)* means 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. This definition of SRM is the same as that used by USDA in its BSE interim final rule declaring SRMs to be inedible and prohibiting their use in human food.

• *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be free of prohibited cattle material or must contain not more than 0.15 percent hexane-insoluble impurities as determined by the method for "hexane-insoluble matter" in the 5th edition of the *Food Chemicals Codex*, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity. You may obtain a copy of the above-referenced method from the Division of Dairy and Egg Safety (HFS–306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD or at the Office of the **Federal Register**, 800 North Capitol St., NW., suite 700, Washington, DC.

• *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

III. The Proposed Recordkeeping Requirements

A. Proposed Recordkeeping Requirements

We are proposing in §§ 189.5(c)(1) and 700.27(c)(1) 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 demonstrate that the material from cattle meets the requirements of the interim final rule. 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 the suppliers of cattle material to demonstrate that their source material is free from prohibited cattle material. Similarly, without adequate records, FDA may not know whether manufacturers and processors of human food and cosmetics have complied with the prohibitions against the use of prohibited cattle materials. Therefore, we are proposing under §§ 189.5(c)(1) and 700.27(c)(1) that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate that the human food and cosmetics do not contain prohibited cattle materials and that such records must be made available to FDA for inspection and copying.

For example, to satisfy the requirement in §§ 189.5(c)(1) and 700.27(c)(1) of this proposed rule that records must show the absence of specified risk materials, manufacturers and processors of human food and cosmetics that are manufactured with, processed from, or otherwise contain, brain from cattle would have to establish and maintain records to demonstrate, among other things, that the human food or cosmetic was not manufactured with, processed from, or does not otherwise contain, brain from cattle over 30 months of age.

In general, we would expect a manufacturer or processor of FDA-regulated human food or cosmetics containing cattle material (e.g., soup containing beef

broth, dietary supplements containing cattle brain powder) to have the following types of records:

• A signed and dated affirmation (with contact information) by the slaughter establishment that cattle material supplied by that establishment in a particular shipment does not contain prohibited cattle materials. If lots of cattle material from different slaughter establishments are pooled into a final product, then a manufacturer or processor would need to maintain records from each slaughter establishment.

• For human food and cosmetics containing tallow, a manufacturer or processor would need to maintain records from a slaughter establishment affirming that the tallow was produced from material containing no prohibited cattle materials or similar records (i.e., signed, dated, with contact information) from the tallow supplier affirming that the tallow contains no more than 0.15 percent hexane-insoluble impurities.

We request comments on other ways in which the proposed recordkeeping requirements might be satisfied. We also request comments on whether existing recordkeeping practices include the required information and, if not, what changes the proposal would necessitate.

We note that USDA is working toward the establishment of a national database for animal identification, which should make maintaining information about source animals less burdensome.

We are proposing in §§ 189.5(c)(2) and 700.27(c)(2) that records be retained for 2 years after the date the records were created. We acknowledge that USDA in its BSE interim final rule is requiring that records be retained for 1 year. However, FDA-regulated human food, such as canned and dried foods and dietary supplements and cosmetics have a longer shelf life than most USDA-

regulated products, which are primarily fresh meat. It is important for traceback and recall purposes that records be retained for the likely shelf life of the product. As discussed previously, records documenting the absence of prohibited cattle materials in human food and cosmetics are necessary to help FDA ensure compliance with the requirements of the interim final rule. It is important for the records to be kept during the shelf life of these products, so that FDA can ensure that products on the market are not adulterated. Therefore, we have tentatively concluded that records must be retained for 2 years.

We are proposing in §§ 189.5(c)(3) and 700.27(c)(3) that records be maintained at the manufacturing or processing establishment or at a reasonably accessible location. Proposed §§ 189.5(c)(4) and 700.27(c)(4) provide that maintenance of electronic records is acceptable and that electronic records are considered to be reasonably accessible if they are accessible from an onsite location.

Proposed §§ 189.5(c)(5) and 700.27(c)(5) provide that records required by this subpart must be available to FDA for inspection and copying.

Because we do not necessarily have access to records maintained at foreign establishments, we are proposing in §§ 189.5(c)(6) and 700.27(c)(6), respectively, that importers must electronically affirm their compliance with the recordkeeping requirements in §§ 189.5(c)(1) and 700.27(c)(1), respectively, at the time of entry into the United States of human food or cosmetics manufactured from, processed with, or otherwise containing, material from cattle and must provide the required records within a reasonable time if requested. The records we would expect are similar to those described above for domestic products. In order for importers to electronically affirm

compliance, FDA intends to modify our electronic entry system to provide a field where importers can tell us that they have the required BSE records. Proposed §§ 189.5(c)(7) and 700.27(c)(7) provide that records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in 21 CFR 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Under the proposed rule, records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations would remain subject to part 11 of this chapter.

B. Legal Authority

Because this proposed rule is a companion rule to the interim final rule, we are issuing this proposed rule under the authorities cited in the interim final rule as well as sections 801(a) and 701(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(a) and 371(b)). As we stated in the interim final rule, FDA is issuing these regulations 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 act (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)). Under section 402(a)(3) of the act, a food is deemed adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." "Otherwise unfit for food" is an independent clause in section 402(a)(3). It does not seem to require that a food be filthy, putrid, or decomposed for it to be "otherwise unfit for food." We conclude that a food can be "otherwise unfit for food" based on health risks. We seek comments on this interpretation. Because of the discovery of a BSE positive cow in the United States and the possibility of disease transmission to humans from exposure to material from infected cattle, prohibited cattle

materials (SRMs, small intestine of all cattle, MS(Beef), material from nonambulatory disabled cattle, and material from cattle not inspected and passed) these materials may present a risk to human health. Under our interpretation of section 402(a)(3), these materials are unfit for food. Under section 402(a)(4) of the act, a food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." The failure to ensure that food is prepared, packed, or held under conditions in which prohibited cattle materials do not contaminate the food constitutes an insanitary condition whereby it may have been rendered injurious to health and thus renders the food adulterated under section 402(a)(4) of the act.

Under section 402(a)(5) of the act, food is deemed adulterated if "it is, in whole or in part, the product * * * of an animal which has died otherwise than by slaughter." Some cattle are not inspected and passed because they have died before slaughter. Material from these cattle that die otherwise than by slaughter is adulterated under section 402(a)(5). We are also relying on the food additive provision in section 402(a)(2)(C) of the act. As a result, because neither a food additive regulation nor an exemption is in effect for prohibited cattle materials intended for use in human food, such materials, with the exception of dietary ingredients in dietary supplements, are adulterated under section 402(a)(2)(C) of the act and their presence in food renders the food adulterated. Under section 601(c) of the act, a cosmetic is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." The failure to ensure that a cosmetic is prepared, packed,

or held under conditions in which prohibited cattle materials do not contaminate the cosmetic constitutes an insanitary condition whereby it may have been rendered injurious to health and, thus, renders the cosmetic adulterated under section 601(c) of the act.

Under section 701(a) of the act, FDA is authorized to issue regulations for the act's efficient enforcement. A regulation that requires measures to prevent human food from being unfit for food, from being or bearing an unsafe food additive, from being the product of an animal that died otherwise than by slaughter, and to prevent human food and cosmetics from being held under insanitary conditions allows for efficient enforcement of the act. These proposed regulations 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 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.

Once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is prohibited cattle material. For example, we would not know from examination of a spinal cord whether the source animal was over 30 months of age at the time of slaughter, or whether it was inspected and passed. 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. Under the proposed 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.

We are also issuing the provisions of this proposed rule related to records regarding imported human food and cosmetics under sections 801(a) and 701(b) of the act. 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. This proposed rule sets out requirements for imported human food and cosmetics to ensure that only products that fully comply with the requirements of the interim final rule are admitted into the United States.

IV. Effective Date and Opportunity for Public Comment

We are proposing that any final rule based on this proposal be effective 30 days after issuance of that final rule.

FDA invites public comment on this proposed rule. The agency will consider modifications to this proposed rule based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Preliminary Regulatory Impact Analysis of the Proposed Rule Recordkeeping Requirements on Materials Derived From Cattle in Human Food and Cosmetics

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including the following conditions: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is not an economically significant regulatory action.

1. Need for Regulation

USDA's BSE interim final rule requires that specified risk materials, small intestine of all cattle, tissue from nonambulatory disabled cattle, and MS(Beef) not be used for human food. SRMs include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process 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. USDA's BSE interim final rule requires that all of the prohibited materials be destroyed or sent to inedible rendering.

FDA, in response to the finding of an adult cow, imported from Canada, that tested positive for BSE in the State of Washington and to be consistent with USDA in regulating cattle products that could potentially transmit BSE, is issuing an interim final rule for FDA-regulated human food and cosmetics that contain cattle material. This proposed recordkeeping rule is a companion to the interim final rule and responds to the same public health concerns. This proposed rule would not affect the incidence of BSE in cattle, which is addressed in other FDA regulations. This proposed rule would serve as an additional safeguard to reduce human exposure to the agent that causes BSE that may be present in cattle-derived products from domestic and imported sources.

2. Proposed Rule Coverage

This proposed rule would require recordkeeping to document compliance with the provisions of the interim final rule that prohibit the use of "prohibited cattle materials." Prohibited cattle materials include SRMs (brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of

the tail, the transverse process 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), small intestine of all cattle, tissue from nonambulatory disabled cattle, tissue from cattle not inspected and passed for human consumption, and MS(Beef).

This proposed rule would require that manufacturers and processors of human foods and cosmetics maintain records indicating that prohibited cattle materials have not been used in the manufacture or processing of a human food or cosmetic, and make such records available to FDA for inspection and copying. There are several reasons for the proposed requirements. First, 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 it is an SRM. Second, without records it may not be possible to determine whether a product contains material from cattle that were not inspected and passed. Third, a product might contain MS(Beef) without its presence being evident from the appearance of the product. Finally, manufacturers and processors might not, without a legal requirement, establish and maintain records to demonstrate that cattle material does not contain prohibited cattle materials. We have tentatively concluded that, to ensure that public health is protected, it is necessary that manufacturers and processors keep records indicating that human food and cosmetics are not manufactured from, processed with, or otherwise contain, prohibited cattle materials. Because we do not necessarily have access to records maintained at foreign establishments, we have included in this proposed rule a requirement that importers of food or cosmetics manufactured from, processed with, or otherwise containing, cattle material electronically

affirm their compliance with the relevant recordkeeping requirements in this proposed rule at the time of entry into the United States and provide required records if requested.

3. Costs and Benefits of the Proposed Rule

This proposed rule would require manufacturers and processors of FDA-regulated human food and cosmetics manufactured from, processed with, or otherwise containing, cattle material to maintain records demonstrating that prohibited cattle materials are not used in their products. This proposed rule would require that the manufacturer or processor retain records for 2 years after using the cattle material in food or cosmetics. Records must be kept at the manufacturing or processing establishment or another reasonably accessible location. Manufacturers and processors must provide FDA with access to the required records for inspection and copying.

a. *Costs of proposed rule.* FDA used establishment data from the FDA Small Business Model (which includes information on all establishments in a manufacturing sector regardless of size) (Ref. 1) to determine the number of food manufacturers and processors that will need to comply with the proposed recordkeeping requirements. The model contains information on the number of establishments in certain food producing sectors but does not have information on specific ingredients used by the food establishments in making products. Data from the model indicates that 181 establishments produce spreads, 127 establishments produce flavoring extracts, 40 establishments produce canned soups and stews, 625 establishments produce nonchocolate candy, 88 establishments produce yogurt, and 451 establishments produce ice cream. FDA cannot verify that all of these establishments actually use cattle materials that fall under the jurisdiction of this proposed rule; many may not.

It is likely that all of the 132 establishments that produce fats and oils currently use tallow derivatives, not tallow, so FDA assumes that no records will be required to be kept by this establishment group. We assume that only 25 percent of the establishments from the remaining production sectors listed above actually produce food that is manufactured from, processed with, or otherwise contains, material from cattle and are therefore required to keep records. We include only 25 percent of the establishments in our estimates because most of the manufacturers likely do not use cattle-derived materials in their products. FDA requests comments on this assumption.

FDA research shows that 25 establishments with U.S. addresses supply cattle-derived ingredients that are used in cosmetics (Ref. 2). These cattle-derived ingredients include albumin, brain extract, brain lipids, cholesterol and cholesterol compounds, fibronectin, sphingolipids, spleen extract, tallow, and keratin and keratin compounds. FDA research also shows that 22 foreign establishments may export these cattle-derived ingredients to U.S. cosmetic manufacturers. These foreign establishments would be required to provide records to their U.S. cosmetic manufacturer customers. We therefore include these foreign establishments when we estimate the recordkeeping costs. Imported cosmetic products represent about 10 to 20 percent of the cosmetic products on U.S. store shelves (Refs. 3, 4, and 5). However, the burden of the interim final rule to foreign cosmetics input suppliers and manufacturers will be less than the burden on domestic cosmetics producers. The burden will be less for foreign cosmetics manufacturers because Europe currently imposes some requirements similar to this rule.

FDA does not have enough information on the precise cattle material used by the 47 domestic and foreign cosmetics establishments to know how often

tallow derivatives (exempt from this proposed rulemaking) are the only cattle-derived ingredient used in these products. We estimate that 75 percent (or 35) of the 47 cosmetics establishments would have to keep records for their cattle-derived ingredients. We estimate only 75 percent will keep records because many cosmetics use tallow derivatives as their only cattle-derived material, and such materials are not covered by the recordkeeping provisions. FDA requests comments on this assumption.

From FDA's dietary supplement database (Ref. 6), we are able to tell that there are 162 dietary supplement brand names that use cattle material as ingredients in their products. We assume that each brand name represents a facility that produces multiple dietary supplement products containing cattle-derived ingredients; therefore we assess recordkeeping costs for all 162 brand names. We do not have information to determine if any of the dietary supplement manufacturers use tallow derivatives (exempt from this recordkeeping requirement) as their only cattle-derived ingredient.

b. *Recordkeeping.* USDA's BSE interim final rule requires those establishments that slaughter cattle or that process the carcasses or parts of carcasses of cattle maintain daily records sufficient to document the implementation and monitoring of procedures for removal, segregation, and disposition of SRMs. USDA's BSE interim final rule requirements will reduce the startup costs of recordkeeping required by this proposed rule.

Recordkeeping costs include one-time costs and recurring costs. One-time costs include the costs of designing records and training personnel in the maintenance of the records. The recurring costs are the costs of ensuring that the records adequately document that the shipment of cattle materials to an FDA-regulated facility is free of prohibited cattle materials. The costs of

retaining records and planning for an FDA request for records access are estimated to be zero. We estimate these costs to be zero because current business practices already dictate that records are kept for at least 1 year for tax purposes and product liability purposes; the marginal private benefit of retaining records for a second year is assumed to be greater than the marginal cost of doing so. Although there is no specific time period for providing records when requested, FDA notes that records requests costs are zero when FDA gives the records submitter 24 hours to comply. These cost estimates are consistent with cost estimates used in FDA's proposed recordkeeping requirements in "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (the Bioterrorism Act proposed recordkeeping rule) (68 FR 25188, May 9, 2003).

We assume that the one-time training burden incurred for each facility is approximately one-third of an hour. This time includes both the training required for personnel to learn how to verify that the appropriate records have been received and/or created, and also the training required for personnel to learn how to file and maintain those records. Given current business practices, we know personnel are familiar with recordkeeping; therefore, the requirement to maintain additional records is expected to be learned quickly. This training burden for recordkeeping is consistent with the recordkeeping training burden in the analysis for the Bioterrorism Act proposed recordkeeping rule (68 FR 25188; May 9, 2003) and the records maintenance burden used in the analysis of the juice HACCP rule (66 FR 6138; January 19, 2001). Consistent with the analysis conducted for the Bioterrorism Act proposed recordkeeping rule, FDA assumes an hourly cost of an administrative worker, $25.10 per hour, which

has been doubled from $12.55 wage per hour to include overhead costs. This cost, $25.10 per hour, applies to all labor costs.

We use the FDA Labeling Cost Model to estimate the one-time records design costs per facility of $1,190 per stock keeping unit (SKU) (Ref. 7). It is likely that facilities using cattle-derived ingredients, whether the ingredients are for human food or cosmetics, will take advantage of their economies of scope and produce more than one product with these ingredients. It is probable that each establishment has several SKUs associated with products containing cattle-derived ingredients that will now require recordkeeping. To account for additional products and SKUs we take the record design costs per facility times 1.5 for a total design cost per facility of $1,785 ($1,095 in labor costs and $690 in capital costs).

We multiplied the cost per product per SKU by 1.5 to account for the additional records design required for the additional SKUs. The record design cost for the first affected product or SKU will be more expensive than the marginal cost of adding records for additional SKUs. This marginal cost of record design for additional SKUs could be negligible or it could come close to doubling the costs; we therefore pick 1.5, the midpoint of 1 and 2, to be the cost multiplier.

Consistent with the analysis conducted for the Bioterrorism Act proposed recordkeeping rule, this record design cost is assumed to be shared between two facilities—the upstream facility and the downstream facility—as both will need to be involved in record production that meets the needs of both the supplier and customer for the cattle-derived ingredient.

Unlike the Bioterrorism Act proposed recordkeeping rule, we do not have direct information on all the facilities covered; we do not have data on the

number of slaughter plants or renderers that supply cattle material for the food and cosmetic manufacturers and processors under FDA jurisdiction. FDA does, however, have some information on the number and type of downstream facilities that receive this material. Using information on the number of food and cosmetic manufacturers that may use cattle-derived ingredients subject to the interim final rule and this proposed rule, we can account for the total shared records costs by assuming that each food manufacturer or processor facility listed in table 1 of this document procures ingredients from one upstream slaughter plant or renderer. It is likely that each manufacturer or processor has a contractual relationship with an upstream slaughterer or renderer. FDA requests comment on whether food manufacturers and processors maintain contractual relationships with one or several cattle-material input suppliers. Information on food producing facilities in table 1 represents U.S. facilities; dietary supplement numbers account for both domestic and foreign facilities; cosmetics numbers account for both domestic and foreign input suppliers.

TABLE 1.—FIRST YEAR RECORDS COSTS

Type of Product Using Cattle Material	Number of Facilities Estimated to Use /cattke Materials	Costs per Facility for Designing Records	Costs per Facility for Training (1/3 hour * $25.10 per Hour)	Total Setup Costs
Canned soups and stews	10	$1,785	$8.37	$17,934
Fats and oils	none			
Flavoring extracts	32	$1,785	$8.37	$57,388
Spreads	45	$1,785	$8.37	$80,702
Candy	156	$1,785	$8.37	$279,766
Yogurt	22	$1,785	$8.37	$39,454
Ice cream	113	$1,785	$8.37	$202,651
Dietary supplements	162	$1,785	$8.37	$290,526
Cosmetics	35	$1,785	$8.37	$62,768
Color additives	none			
Total	575	$1,785	$8.37	$1,031,189

The recurring recordkeeping cost is the cost of ensuring that appropriate records document the absence of prohibited cattle materials in human food and cosmetics. The framework for estimating the amount of time required for FDA-regulated facilities to ensure adequate records for each shipment of materials is based on the regulatory impact analysis of the Bioterrorism Act proposed recordkeeping rule. In that analysis we estimated that 30 minutes per week would be required to ensure that records on each shipment to and from a facility contain adequate information regarding the contents of the package, the transporter, supplier, and receiver.

The recordkeeping requirements of this proposed rule would cover only a small fraction of all ingredients used in the food and cosmetic manufacturing processes and only require that records of cattle-derived ingredient origin from the input supplier be verified and maintained by the food or cosmetic manufacturer and processor. Because this recordkeeping requirement is less complex than the recordkeeping requirements under the Bioterrorism Act and affects fewer ingredients, we estimate the per facility burden to be about one-half of the burden estimated for the Bioterrorism Act proposed recordkeeping rule: 15 minutes per week, or 13 hours per year. FDA assumes that this recordkeeping burden would be shared between two entities (i.e., the slaughter plant and the manufacturer of finished products containing cattle-derived ingredients).

Table 2 of this document shows the recurring recordkeeping costs for food and cosmetics manufacturers that would be needed to comply with this proposed rule. As stated earlier, information on food producing facilities in table 2 represents U.S. facilities; dietary supplement numbers account for both

domestic and foreign facilities; cosmetics numbers account for both domestic and foreign input suppliers.

TABLE 2.—RECURRING ANNUAL RECORDS COSTS

Type of Product (From Raw or Rendered Material that Needs Accompanying Documentation)	Number of Facilities	Annual Costs per Facility of Ensuring that Appropriate Records Accompany Each Shipment Received (13 Hours * $25.10 per Hour)	Total recurring annual costs
Canned soups and stews	10	$326.30	$3,263
Fats and oils	none		
Flavoring extracts	32	$326.30	$10,442
Spreads	45	$326.30	$14,684
Candy	156	$326.30	$50,903
Yogurt	22	$326.30	$7,179
Ice cream	113	$326 30	$36,872
Dietary supplements	162	$326.30	$52,861
Cosmetics	35	$326.30	$11,421
Color additives	none		
Total	575	$326 30	$187,625

c. *Benefits of the proposed rule.* The benefits of this proposed rule are derived from the benefits of the interim final rule, which are the value of the public health benefits. The public health benefit is the reduction in the risk of the human illness associated with consumption of the agent that causes BSE.

If we define the baseline risk as the expected annual number of cases of variant Creutzfeldt-Jakob disease (vCJD) per year, then the annual benefits of prohibiting prohibited cattle materials for use in foods and cosmetics would be:

(baseline annual cases of vCJD—annual cases of vCJD under FDA interim final rule) x (value of preventing a case of VCJD).

An alternative way to characterize benefits is:

Reduction in annual cases in vCJD under FDA interim final rule x (value of preventing a case of vCJD).

We do not know the baseline expected annual number of cases. But based on the epidemiology of vCJD in the United Kingdom, we anticipate much less

than one case of vCJD per year in the United States. Because the interim final rule and this proposed rule would reduce rather than eliminate risk of exposure to BSE infectious materials, the reduction in the number of cases will be some fraction of the expected number. The value of preventing a case of vCJD is the value of a statistical life plus the value of preventing a year-long or longer illness that precedes certain death for victims of vCJD. In a recent rule making regarding labeling of trans fatty acids (68 FR 41434, July 11, 2003), we used a range of $5 million to $6.5 million for the value of a statistical life. The value of preventing a vCJD case would be even higher because of the significant medical costs associated with the illness (Ref. 8). We estimate that the value of preventing a single case of vCJD ranges from $5.7 million to $7.1 million. This estimate includes direct medical costs, reduced ability of the ill person to function at home and at work, and the cost of premature death.

As discussed in the companion interim final rule, the Harvard-Tuskegee study has stated that a ban on specified risk materials, including cattle brains, spinal cord and vertebral column, from inclusion in human and animal food would reduce the very few potential BSE cases in cattle by a further 88 percent and potential human exposure to infectivity in meat and meat products by a further 95 percent. The interim final rule, in conjunction with USDA's BSE interim final rule, will help achieve this reduction in potential human exposure. The interim final rule will also reduce potential human exposure to BSE infectivity in other human food not covered by the Harvard-Tuskegee study. This proposed rule would help ensure that the provisions of the interim final rule are carried out. For example, this proposed rule will require documentation that a domestically produced or foreign-produced dietary

supplement or ingredient contains cattle material (e.g., brain) only from animals of an appropriate age.

d. *Summary of costs and benefits of proposed rule.* For this proposed rule, the costs are to setup and then to maintain a recordkeeping system to document all cattle-derived ingredients, except tallow derivatives, used in FDA-regulated food and cosmetics. The setup costs are about $1 million, and the annual costs of maintaining the recordkeeping system are about $200,000. The benefit of this proposed rule is that its requirements will—by requiring records that the provisions of the interim final rule have been followed—provide an additional safeguard against a case of vCJD occurring in humans.

B. Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities.

First year costs of this proposed rule are about $1,800 per facility pair, with this cost divided between the upstream facility (slaughterhouse or rendering plant) and downstream facilities (manufacturers of food or cosmetics). FDA cannot determine if the cost sharing between the two firms would be equal. If the cost sharing is equal, then each facility would have to bear about a $900 first year cost to comply with the recordkeeping required by the proposed rule; if the cost sharing is not equal, then one facility in the partnership may bear zero costs all the way up to the total first year costs of

$1,800. Recurring costs of this proposed rule are about $326 per facility relationship, which may be borne by only one firm or may be shared between facilities.

Using FDA's Small Business Model, we can estimate the number of facilities, when recordkeeping costs are shared and when they are not shared, that may go out of business as a result of this proposed rule.

Table 3 of this document shows that if facilities are only responsible for one-half of the recordkeeping cost burden (the burden is equally shared between the upstream and downstream facilities), then only two very small facilities (less than 20 employees) may be overburdened by having to comply with this proposed rule in a year's time; if the recordkeeping cost burden is borne by only one facility in the business relationship (either the upstream or the downstream firm), then six very small facilities (less than 20 employees) may have trouble complying with this interim final rule and staying in business. Facilities with 20 to 499 employees and facilities with at least 500 employees that must comply with this proposed rule are not in danger of having to stop operating as a result of the proposed rule.

TABLE 3.—POTENTIAL FOR FACILITY SHUTDOWN

Industry	Estimated Number of Facilities Affected	Regulation Burden on Each Facility (Shared Burden or Total Burden)	Number of Facilities in Industry That May Shut Down
Canned soups and stews	10	$900	0
Canned soups and stews	10	$1,800	0
Flavoring extracts	32	$900	0
Flavoring extracts	32	$1,800	0
Spreads	45	$900	0
Spreads	45	$1,800	1
Candy	156	$900	1
Candy	156	$1,800	2
Yogurt	22	$900	0
Yogurt	22	$1,800	0
Ice cream	113	$900	0

TABLE 3.—POTENTIAL FOR FACILITY SHUTDOWN—Continued

Industry	Estimated Number of Facilities Affected	Regulation Burden on Each Facility (Shared Burden or Total Burden)	Number of Facilities in Industry That May Shut Down
Ice cream	113	$1,800	1
Dietary supplements	162	$900	1
Dietary supplements	162	$1,800	2
Cosmetics	35	$900	0
Cosmetics	35	$1,800	0

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is $115 million. FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. The Small Business Regulatory Enforcement Fairness Act of 1996 Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule,

should it become final, would not be a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act Analysis

This proposed rule contains information collections that are subject to review by OMB under the Paperwork Reduction act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual recorkeeping burden included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following 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.

Title: Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

Description: This proposed rule would require records on FDA-regulated human food, including dietary supplements, and cosmetics that are manufactured from, processed with, or otherwise contain, material derived from cattle. This proposed rule is a companion rulemaking to FDA's interim

final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics" published in this issue of the **Federal Register**. This proposed rule would require that manufacturers and processors of human food and cosmetics manufactured from, processed with, or that otherwise contain, material from cattle, maintain records demonstrating that the food or cosmetic has not been manufactured from, processed with, or does not otherwise contain, prohibited cattle materials and make such records available to FDA for inspection and copying. These proposed requirements are necessary because, once materials are separated from an animal, it may not be possible without records to know the following: (1) Whether the cattle materials contains SRMs, (2) whether the material contains small intestine, (3) whether the material was sourced from an animal that was inspected and passed for human consumption, (4) whether the material was sourced from a nonambulatory disabled animal, and (5) whether the product contains MS(Beef). Under the proposed rule, manufacturers and processors must retain records for 2 years at the manufacturing or processing establishment or another reasonably accessible location.

Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Capital Costs	Total Hours
189.5(c), 700.27(c)	575	1	575	44.33	$396,750	25,490
189.5(c), 700.27(c)	575	52	29,900	0.25	$0	7,475
Total one time burden hours						25,490
Total recurring burden hours						7,475

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

Burden:

Hour Burden Estimate

FDA has determined that there are 575 facility relationships, consisting of the following facilities: A producer of cattle materials requiring records—this may be a slaughterhouse or renderer (the upstream facility) and a purchaser of cattle 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 carry the burden necessary to comply with this proposed rule; therefore we estimate the time burden of developing these records as a joint task between the two facilities.

One Time Burden

The first year burden of the proposed recordkeeping requirement consists of the facilities training their employees on how to keep the records necessary to comply with this proposed rule and designing the records. The one-time training burden incurred for each facility is assumed to be the equivalent of 1 month's worth of on-the-job training or approximately one-third of an hour. This time includes both the training required for personnel to verify that appropriate records have been received and/or created, and also the training required by personnel to file and maintain those records. Therefore, the total one-time training burden is 575 x 0.33 hrs = 190 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 $1,095 in labor costs (and $690 in

capital costs which we deal with in the next section). 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 575 facilities to get an estimated total training and design burden of 25,490 hours.

Table 4 row 1 of this document shows the total hour burden from training and records design to be 44.33 hours per facility x 575 record keepers = 25,490 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 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 slaughter plant and the manufacturer of finished products containing cattle-derived ingredients). Therefore the total recurring burden will be 13 hrs x 575 = 7,475 hours, as shown in row 2 of table 4 of this document.

Capital Cost and Operating and Maintenance Cost Burden

We use the FDA Labeling Cost Model to estimate the one-time records 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 575 = $396,750. These one time costs are shown in row 1 of table 4 of this document.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to fax comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer, FDA, FAX: 202–395–6974.

VII. Environmental Impact Analysis

The agency has determined under 21 CFR 25.30(h) that this action is a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

1. Model for Estimating the Impacts for Regulatory Costs on the Survival of Small Businesses and its Application to Four FDA-Regulated Industries, Final Report, Eastern Research Group, July 2002.

2. CTFA International Buyer's Guide, produced by the Cosmetics, Toiletries, and Fragrances Association (CTFA) found on the Internet at *http://www.ctfa-buyersguide.org.*

3. Memorandum of Telephone Conversation, Dr. Gerald McEwen, Cosmetic, Toiletry, and Fragrance Association and Karen L. Carson, Food and Drug Administration, June 29, 2004.

4. United States International Trade Commission Interactive Tariff and Trade DataWeb, Essential Oils and Resinoids; Perfumery, Cosmetic or Toilet Preparations. Accessed online at *http://dataweb.usitc.gov.*

5. U.S. Census Bureau, 1997 Economic Census: Bridge Between NAICS and SIC Manufacturing. Accessed online at *http://www.census.gov.*

6. FDA Dietary Supplement Products with Animal Ingredients Database (DSPD–A), September 2002, RTI International, contractor—FDA Contract Number 06673.013

7. FDA Labeling Cost Model, Final Report, Muth, M. K., E. C. Gledhill, and S. A. Karns, RTI, Health, Social, and Economics Research, Research Triangle, NC, April 2002.

8. Memorandum to the Record, The Costs of a Case of Variant Creutzfeldt-Jakob disease (vCJD), 2004.

List of Subjects

21 CFR Part 189

Food additives, Food packaging, Substances prohibited from use in human food.

21 CFR Part 700

Cosmetics, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration proposes to amend 21 CFR parts 189 and 700 as follows:

* * * * *

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

1. The authority citation for 21 CFR part 189 is revised to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371, 381.

2. Section 189.5 is amended by revising paragraph (c) to read as follows:

§ 189.5 Prohibited cattle materials.

* * * * *

(c)(1) Records. Manufacturers and processors of human food that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records sufficient to demonstrate that the food is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

(2) Records must be retained for 2 years after the date the records were created.

(3) Records must be retained at the manufacturing or processing establishment or at a reasonably accessible location.

(4) The maintenance of electronic records is acceptable. Electronic records are considered to be reasonably accessible if they are accessible from an onsite location.

(5) Records required by this subpart must be available to FDA for inspection and copying.

(6) Importers must electronically affirm their compliance with the recordkeeping requirements in paragraph (c)(1) of this section at the time of

entry into the United States of human food manufactured from, processed with, or otherwise containing, material from cattle and must, if requested, provide the required records within a reasonable time.

(7) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

* * * * *

PART 700—GENERAL

3. The authority citation for 21 CFR part 700 continues to read as follows:

Authority: 21 U. S. C. 321, 331, 352, 355, 361, 362, 371, 374.

4. Section 700.27 is amended by revising paragraph (c) to read as follows:

§ 700.27 Use of prohibited cattle materials from cattle in cosmetic products.

* * * * *

(c)(1) Records. Manufacturers and processors of a cosmetic that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

(2) Records must be retained for 2 years after the date the records were created.

(3) Records must be retained at the manufacturing or processing establishment or at a reasonably accessible location.

(4) The maintenance of electronic records is acceptable. Electronic records are considered to be reasonably accessible if they are accessible from an onsite location.

(5) Records required by this subpart must be available to FDA for inspection and copying.

(6) Importers must electronically affirm their compliance with the recordkeeping requirements in paragraph (c)(1) of this section at the time of entry into the United States of cosmetics manufactured from, processed with, or otherwise containing, material from cattle and must, if requested, provide the required records within a reasonable time.

(7) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

* * * * *

Dated: July 8, 2004

July 8, 2004.

Lester M. Crawford,
Acting Commissioner of Food and Drugs.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL