The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If this emergency regulation is later deemed significant under DOT Regulatory Policies and Procedures, we will prepare a final regulatory evaluation and place it in the AD Docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation, if filed.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2006–20–51 Boeing: Amendment 39–14786. Docket No. FAA–2006–26028; Directorate Identifier 2006–NM–222–AD.

Effective Date

(a) This AD becomes effective October 16, 2006, to all persons except those persons to whom it was made immediately effective by emergency AD 2006–20–51, issued on September 30, 2006, which contained the requirements of this amendment.

Affected ADs

(b) None.

Applicability

(c) This AD applies to airplanes in Table 1 of this AD certificated in any category.

TABLE 1.—APPLICABILITY

Boeing model	Powered by General Electric (GE) model
(1) 777–200LR series airplanes	GE90–110B engines.
(2) 777–300ER series airplanes	GE90–115B engines.

Unsafe Condition

(d) This AD results from a report of two occurrences of engine thrust rollback during takeoff. The Federal Aviation Administration is issuing this AD to prevent dual-engine thrust rollback, which could result in the airplane failing to lift off before reaching the end of the runway or failing to clear obstacles below the takeoff flight path.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Revision of the Airplane Flight Manual (AFM)

(f) Within 24 hours after the effective date of this AD, revise the Certificate Limitations Section of the AFM to include the following statement. This may be done by inserting a copy of this AD into the AFM.

''Use of reduced thrust takeoff ratings determined by either the assumed temperature method or the fixed de-rate method or a combination of both, is prohibited. Full-rated thrust must be used for takeoff.''

Note 1: When a statement identical to that in paragraph (f) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

Special Flight Permit

(g) Special flight permits, as described in Section 21.197 and Section 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199), are not allowed.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Issued in Renton, Washington, on October 2, 2006.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–16670 Filed 10–10–06; 8:45 am]

BILLING CODE 4910–13–P

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: Final rule.

SUMMARY: The Food and Drug Administration (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 sufficient to demonstrate that the human food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. These recordkeeping requirements provide documentation for the provisions in FDA's interim final rule entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics.'' FDA is requiring recordkeeping because manufacturers and processors of human food and cosmetics need records to ensure that their products do not contain prohibited cattle materials, and records are necessary to help FDA ensure compliance with the requirements of the interim final rule.

DATES: This rule is effective on January 9, 2007.

FOR FURTHER INFORMATION CONTACT: Rebecca 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

On July 14, 2004, FDA proposed a rule entitled ''Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle'' (the proposed rule) (69 FR 42275) to 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 the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. The proposed rule was a companion rulemaking to FDA's interim final rule (IFR) entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics'' (the IFR) (69 FR 42256). We believe that records sufficient to demonstrate 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 prohibited cattle materials. Therefore, we are finalizing the proposed rule to 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 human food and cosmetics are not manufactured from, processed with, or do not otherwise contain, prohibited cattle materials. We also are finalizing the provision in the proposed rule that these records must be made available to FDA for inspection and copying. FDA notes that the requirement in the IFR that existing records relevant to compliance be made available to FDA remains and has been incorporated into the final record provisions.

In response to the December 2003 finding of an adult cow—imported from Canada—that tested positive for bovine spongiform encephalopathy (BSE) in the State of Washington, FDA published the IFR requiring that specified risk materials (SRMs), small intestine of all cattle, tissue from nonambulatory disabled cattle, tissue from cattle not inspected and passed for human consumption, and mechanically separated beef (MS beef) not be used for FDA-regulated human food and cosmetics.[1] 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, as well as the tonsils and distal ileum of the small intestine of all cattle.

The U.S. Department of Agriculture (USDA) also published an IFR (69 FR 1862, January 12, 2004) to prohibit certain cattle material from use in human food. FDA's IFR extended the protection from BSE provided under USDA's BSE IFR to FDA-regulated human food and cosmetics. On September 7, 2005, both FDA (70 FR 53063) and USDA (70 FR 53043) published amendments to their respective IFRs to allow the use of small intestine in human food and cosmetics provided the distal ileum has been removed. This final rule on recordkeeping will help ensure compliance with the provisions of FDA's IFR and, thereby, will serve as an additional safeguard to reduce human exposure to the agent that causes BSE that may be present in human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle.

FDA believes that these recordkeeping requirements are necessary for manufacturers and processors to ensure that all cattle material they use is free from prohibited cattle materials. Furthermore, these requirements are necessary for 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 an SRM. 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.

FDA received 32 responses, each containing one or more comments, from industry, consumers, and other stakeholder groups in response to the proposed rule. We have responded in this document to the comments that were within the scope of this rulemaking. We received several comments that pertained to the prohibitions on the cattle materials themselves, as opposed to the recordkeeping requirements, and other issues that are covered in the IFR. We will be responding to those comments when we finalize the IFR.

II. Response to Comments

A. Who Has to Keep Records? (§§ 189.5(c)(1) and 700.27(c)(1) (21 CFR 189.5(c)(1) and 700.27(c)(1)))

(Comment) We received several comments stating that only the manufacturer or processor of a finished product should have to maintain the required records. Conversely, other comments suggested that only the manufacturer or processor of an ingredient that directly incorporates cattle material from a slaughterhouse or a rendering establishment should have to keep records. The comments requesting that finished product manufacturers keep records stated that it was appropriate that the recordkeeping responsibility should be placed at the finished product stage because, in some cases, an ingredient manufacturer would be making an ingredient that may or may not be incorporated into a food or cosmetic; therefore, the ban on the use of prohibited cattle materials should not apply to the ingredient at the time of production. The comments that stated the opposite view maintained that only the ingredient manufacturers who are obtaining cattle material from slaughterhouses or rendering establishments know whether or not prohibited cattle materials were incorporated into the ingredient, so it is appropriate that the records be maintained by those who have firsthand knowledge of the source of the cattle material.

Comments also requested that rendering establishments and other similar establishments maintain additional records because they handle prohibited cattle materials. These records would include plans to prevent cross-contamination and cleaning and disinfection records.

We also received several comments requesting that we clarify that manufacturers and processors of certain cattle-derived products (e.g., tallow derivatives and milk and milk products) do not have to keep records because their products are exempt in the IFR.

(Response) We believe that manufacturers and processors of human food and cosmetics as well as ingredients used to produce human food and cosmetics must maintain records. To ensure that a finished human food or cosmetic does not contain prohibited cattle materials, it is necessary to ensure that all of the ingredients are free of prohibited cattle materials. This

[1] In June 2005, USDA confirmed the second case of BSE in the United States in a cow born in Texas.

requires information from ingredient suppliers as well as from the finished product manufacturer. A buyer who purchases cattle material from its producer or manufacturer (e.g., from a slaughter or rendering establishment) is in a better position than subsequent purchasers further downstream in the distribution chain to ensure that the purchased cattle material is free from prohibited cattle material. Manufacturers and processors who use ingredients made of cattle material and incorporate it into final products can only ensure that the final products are free of prohibited cattle material if the upstream suppliers have done the same. Therefore, we have concluded that manufacturers and processors of finished human food and cosmetic products, as well as the manufacturers and processors who supply ingredients (e.g., tallow or gelatin) for those finished products, must maintain records.

We are not specifying particular additional records that must be kept by establishments that handle both prohibited and nonprohibited cattle materials. We note that food establishments are subject to the current good manufacturing practice requirements in 21 CFR part 110 and that the failure to take adequate measures to prevent cross-contamination could result in unsanitary conditions whereby the food may be rendered injurious to health and, therefore, adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(4)).

Comments asked that we clarify that manufacturers and processors of certain cattle-derived products (e.g., tallow derivatives and milk and milk products) are exempt from the recordkeeping requirements because these products are exempt from the provisions of the IFR. In the **Federal Register** of September 7, 2005 (70 FR 53063), FDA published amendments to the IFR. In that document, we also clarified that milk and milk products, hides and hide-derived products, and tallow derivatives are excluded from the definition of prohibited cattle materials. We are not requiring that records be kept for cattle materials that are specifically exempted from the definition of ''prohibited cattle material'' without restrictions, such as milk and milk products, hides and hide-derived products, and tallow derivatives. Although §§ 189.5(a)(1) and 700.27(a)(1) exclude tallow that contains no more than 0.15 percent insoluble impurities from the definition of prohibited cattle materials, tallow is not exempt from records requirements because there are restrictions on either the amount of insoluble impurities it contains or the cattle material from which it is sourced.

B. What Type of Records Must Manufacturers and Processors of Human Food and Cosmetics Keep? (§§ 189.5(c)(1) and 700.27(c)(1))

(Comment) We received several comments related to the type of records that must be kept. Most stated that a requirement for lot-by-lot records for human food and cosmetics was overly burdensome relative to the risk posed by BSE. Many comments suggested that maintenance of a continuing letter of guarantee, renewable annually, would be sufficient to ensure that manufacturers and processors are not using prohibited cattle materials in their products.

Other comments stated that lot-by-lot records were necessary, particularly for imports. Some comments suggested that lot-by-lot records should be kept and should contain enough information to allow downstream tracing of the product and upstream tracing of products or ingredients.

(Response) We are requiring in §§ 189.5(c)(1) and 700.27(c)(1) that manufacturers and processors of human food and cosmetics manufactured from, processed with, or that otherwise contain, material from cattle maintain records sufficient to demonstrate that the human food and cosmetics are not manufactured from, processed with, or otherwise contain, prohibited cattle material. We recommend that manufacturers and processors accomplish this in part by maintaining 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 the cattle material or product manufactured from, processed with, or otherwise containing, cattle material. We intend to publish guidance describing in detail the types of records we recommend that manufacturers and processors maintain to demonstrate compliance with the ban on prohibited cattle materials.

Because we do not easily have access to records maintained at foreign establishments, we have included in this final rule a requirement, in §§ 189.5(c)(6) and 700.27(c)(6), that when filing 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 applicable requirements. In addition, if a human food or cosmetic is manufactured from, processed with, or otherwise contains, cattle material, the importer of record must, if requested, provide within 5 days records 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.

We have made several changes to the import provision in the proposed rule. First, we have clarified that the import provision is applicable to the importer of record because the importer of record is responsible for compliance with import requirements. Second, we have added a requirement for the importer of record to affirm that a human food or cosmetic is manufactured from, processed with, or otherwise contains, cattle material. FDA believes that the addition of this affirmation will minimize the number of importers affirming compliance based on the complete absence of cattle material and will help FDA focus its compliance efforts on products manufactured from, processed with, or otherwise containing, cattle material. We have also changed the time period for providing records from a ''reasonable time'' to 5 days. FDA believes that providing a specific time period will eliminate ambiguity and thereby facilitate compliance. FDA further believes that 5 days is a reasonable amount of time for the importer of record to provide the records while still allowing FDA sufficient time to review the documents to make an initial admissibility decision before the conditional release period for the product expires. If the importer of record fails to provide adequate records within 5 days, the product will be subject to detention because it appears to be adulterated under section 801 of the act (21 U.S.C. 381), and the owner or consignee will be afforded notice and an opportunity for hearing in accordance with section 801(a) of the act.

With regard to the comments that stated that the records required should allow tracing of the product in the event

of a recall, we agree that it is beneficial to have records that will allow for trace-back or trace-forward activities. We intend to recommend records in a guidance document that, in addition to being essential to ensure compliance, will provide useful information in the event of trace-back or trace-forward activities. We note that some manufacturers and processors of human food may already be maintaining such records as part of ordinary business practices to comply with FDA's recordkeeping requirements in ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (the Bioterrorism Act recordkeeping rule) (69 FR 71562, December 9, 2004).

C. Should There Be a Requirement That Records Be Certified?

(Comment) Several comments suggested that any records required should be certified by an appropriate government authority or that the required records be traceable to a record certified by a government authority. Other comments requested that FDA accept the certification of records by foreign governments, if those authorities choose to certify compliance with our records requirements. One comment suggested that records be certified for compliance through independent audit, though not necessarily by a government, and that FDA require documentation of the certification.

(Response) We do not agree that records need to be certified by an appropriate authority, governmental or otherwise. We did not propose certification in the proposed rule because we did not believe it was necessary to ensure compliance with the rule. In addition, we do not traditionally require certification for other FDA-regulated human food and cosmetic products with records requirements (e.g., seafood and juice hazard analysis critical control points (HACCP) records).

D. How Long Must the Records Be Kept? (§§ 189.5(c)(2) and 700.27(c)(2))

(Comment) We received several comments regarding the length of time that records must be retained. Several comments stated that the required records should be maintained for 1 year after the date they were created to be consistent with USDA's IFR. One comment suggested that the required records be maintained for 3 years after the date they were created to cover the potential shelf life of the products and any potential need to trace back products. Another comment suggested that records be retained for 40 years after the date they were created because variant Creutzfeldt-Jakob disease (vCJD) has a long incubation period, and the records retention requirement should be commensurate with the potential for outbreak of disease. Finally, several comments requested that the records retention requirement vary with the expected shelf life of the human food or cosmetic, but should be no longer than 2 years.

(Response) We proposed in §§ 189.5(c)(2) and 700.27(c)(2) that all required records be retained for 2 years after the date the records were created. The comments received have not persuaded us to change this requirement. The recordkeeping requirement is intended to ensure compliance with the ban on the use of prohibited cattle material. FDA will verify compliance during inspections of facilities that use cattle material directly or that use human food or cosmetics manufactured from, processed with, or that otherwise contain, cattle material. We believe that a 2-year record retention requirement is an appropriate length of time for achieving the goal of this rulemaking. A 2-year record retention requirement will create a compliance history for the establishment. Furthermore, many of the products (e.g., canned soups, gelatin, dietary supplements, and cosmetics) that include material from cattle have shelf lives of several years. A 2-year record retention period will enable FDA to determine compliance of products on the market.

We do not agree that the records retention time should vary with the shelf life of the product as it does in the Bioterrorism Act recordkeeping rule. It is the goal of that rule to allow for trace-back or trace-forward activities of food in an emergency; thus, shelf life of products was the critical determinant of the records retention period. In contrast, our goal in this rulemaking is to ensure compliance with the ban on the use of prohibited cattle material. As stated previously, the 2-year record retention requirement will enable creation of a compliance history for establishments over an extended period of time. Finally, we do not agree that the long incubation period of vCJD necessitates that records be retained for 40 years. This rulemaking is not intended to create a consumption or use history for individuals. Because vCJD has a long incubation period, potentially decades, it would be impractical to try to match disease development with previous consumption or use of a specific commodity.

It will be necessary for inspectors to review and copy records during an inspection. A review of records is one way that we can determine whether an establishment is complying with the ban on the use of prohibited cattle material. It is also important that we be able to copy the required records. We may consider it necessary to copy records when, for example, our investigators need assistance in reviewing a certain record from relevant experts in our headquarters. If we are unable to copy records, we would have to rely solely on our investigator's notes and reports when drawing conclusions. Finally, copying records will facilitate followup regulatory actions.

E. When Do Manufacturers and Processors Have to Comply With the Recordkeeping Requirements?

(Comment) We received several comments requesting that industry be given 90 days after publication of this final rule to comply with the recordkeeping requirements, rather than the proposed 30 days. The comments requested the additional time because they stated that 30 days was not long enough to implement a new recordkeeping protocol in their establishments.

(Response) As we stated in the proposed rule, the agency believes that recordkeeping and records access requirements are necessary immediately. However, because we recognized that recordkeeping systems could not be put in place immediately, we did not include such provisions in the IFR but rather proposed them. The requirements in this rule are no more than are necessary for manufacturers, processors, and importers of record to ensure their compliance with the rule, and we informed industry of the anticipated timeframe for implementation in the proposed rule. These recordkeeping requirements are vital to ensuring compliance with the ban on the use of prohibited cattle material, and we strongly encourage industry to begin keeping them as soon as possible. However, in light of these comments we have decided to make these recordkeeping requirements become effective 90 days after the publication of this final rule in the **Federal Register**.

F. Legal Authority

(Comment) We received a comment that maintained that FDA has no authority to require manufacturers to disclose company records to inspectors.

(Response) We disagree with this comment because the agency has authority under the act both to require maintenance of records and to compel official access to such records for the

efficient enforcement of the act. The act's statutory scheme, taken as a whole, including provisions related to adulteration, prohibited acts, injunction, and seizure, makes clear that FDA has authority to issue a regulation requiring recordkeeping and access to the records that are kept. Viewing the act in its entirety, the United States Court of Appeals for the District of Columbia Circuit has found that the agency has authority to require records notwithstanding the act's lack of express, general authority for records. (*National Confectioners Ass'n* v. *Califano*, 569 F.2d 690 (DC Cir. 1978)). The Supreme Court has recognized that FDA has authority that ''is implicit in the regulatory scheme, not spelled out in haec verba'' in the statute (*Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973)). Indeed, ''it is a fundamental principle of administrative law that the powers of an administrative agency are not limited to those expressly granted by the statutes, but include, also, all of the powers that may fairly be implied therefrom. * * * In the construction of a grant of powers, it is a general principle of law that where the end is required the appropriate means are given and that every grant of power carries with it the use of necessary and lawful means for its effective execution'' (*Morrow* v. *Clayton*, 326 F.2d 35, 44 (10th Cir. 1963)).

In *Toilet Goods Ass'n, Inc.* v. *Gardner* (387 U.S. 158 (1967)), cosmetic manufacturers and distributors challenged an FDA regulation, issued under authority of the Color Additive Amendments of 1960 and section 701(a) of the act (21 U.S.C. 371(a)),[2] authorizing FDA to stop certifying the color additives of any person who had refused to provide FDA with access to its manufacturing facilities, processes, and formulae. The cosmetic manufacturers and distributors argued that the regulation exceeded FDA's statutory authority and maintained that FDA had long sought Congressional authorization for the access required by the regulation but had been denied that power, except for prescription drugs (*id.* at 162). In finding that the controversy was not ripe for review, the Supreme Court set forth an approach to determining FDA's rulemaking authority under section 701(a) that extends beyond consideration of whether a specific section of the act includes a particular requirement. Rather, the approach extends to consideration of the act as a whole and the need to accomplish its purposes:

> Whether the regulation is justified thus depends, not only, as petitioners appear to suggest, on whether Congress refused to include a specific section of the Act authorizing such inspections, although this factor is to be sure a highly relevant one, but also on whether the statutory scheme as a whole justified promulgation of the regulation. This will depend not merely on the inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets.

Id. at 163–64 (internal citation omitted).

In *National Confectioners Ass'n* v. *Califano* (569 F.2d 690 (DC Cir. 1978)), the United States Court of Appeals for the District of Columbia Circuit cited *Toilet Goods* in upholding an FDA regulation, issued under the authority of sections 701(a) and 402(a)(4) of the act,[3] requiring recordkeeping by candy manufacturers (*id.* at 691). The Association challenged FDA's recordkeeping requirement on several grounds, including that it exceeded FDA's statutory authority. The DC Circuit rejected the Association's analysis of FDA's statutory authority as ''unreasonably cramped'' and considered enforcement practicalities as suggested by the Supreme Court in *Toilet Goods:*

> There is no persuasive evidence that Congress intended to immunize food manufacturers from * * * record-keeping. Therefore, in assessing the validity of regulations promulgated under section 701(a) for the efficient enforcement of the Act, we must consider ''whether the statutory scheme as a whole justified promulgation of the regulation.'' *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158, 163 (1967). The consideration concerns ''not merely an inquiry into statutory purpose'' but also practicalities, such as ''an understanding of what types of enforcement problems are encountered by the FDA (and) the need for various sorts of supervision in order to effectuate the goals of the Act.'' *Id.* at 163–64. The Act is not concerned with purification of the stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics. *United States* v. *Urbuteit*, 335 U.S. 355, 357–58 (1948).

Id. at 613 (footnote omitted).

In *National Confectioners*, the DC Circuit considered the act's statutory scheme as a whole, specifically citing certain of the act's provisions relating to adulteration, prohibited acts, injunction, and seizure. Viewing the act in its entirety, the court found no basis to distinguish between FDA's roles in preventing and in remedying commerce in adulterated foods (*id.* at 693). The court concluded that FDA's intention to prevent the introduction of adulterated foods into commerce and to hasten their removal from circulation once there ''reflect the objective of the Act and carry out its mandate'' (*id.* at 694). The regulation upheld in *National Confectioners* required the creation and retention of records by candy makers of the initial distribution of candy. Although FDA's access to the records was not explicitly addressed, the DC Circuit implicitly recognized that FDA had the authority to access those records: In particular, the court stated that ''[r]egulations that require source codes and distribution records may be based legitimately on the need to expedite seizure when voluntary recalls are refused'' (*id.* at 695). The only way for records to expedite seizure is if FDA has access to them.

The comment questioning FDA's authority to inspect records cites the Bioterrorism Act's specific grant of authority to FDA to access certain records as ''proof that neither FDA nor Congress believes that the agency has general statutory power to require records inspection for food.'' FDA's belief in its statutory power to inspect food records is evident in the records requirements it has previously issued, such as regulations that provide FDA with access to records for fish and fishery products (21 CFR 123.9(c)) and records for juice (21 CFR 120.12(e)). Further, the Bioterrorism Act provides in section 306 (21 U.S.C. 414), Maintenance and Inspection of Records, that ''[t]his section shall not be construed * * * to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this Act.'' In addition, Congress indicated its understanding of FDA's records authority in the legislative history of the Bioterrorism Act. The Conference Committee responsible for the Bioterrorism Act acknowledged FDA's recordkeeping authority independent of the Bioterrorism Act in a joint explanatory statement:

> The Managers did not adopt a Senate proposal to authorize the Secretary to require the maintenance and retention of other records for inspection relating to food safety, because the Secretary has authority under section 701(a) of the [Act] to issue regulations for the ''efficient enforcement of this Act'' and this authority, in combination with other

[2] Section 701(a) provides that ''[t]he authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.''

[3] Section 402(a)(4) states that a food shall be deemed 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.''

provisions (such as section 402), gives the Secretary the authority to require appropriate record keeping in food safety regulations.

H.R. Conf. Rep. No. 107–481, at 135 (2002).

The comment questioning FDA's authority to inspect food records further argues that ''if Congress had intended FDA to have broad records inspection authority, section 703, [Records of Interstate Shipment], would have been completely superfluous and meaningless.'' As FDA recognized in a previous rulemaking, the *National Confectioners* court concluded that ''the narrow scope of section 703 of the act is not a limitation on the right of the agency to require recordkeeping and have access to records that are outside the scope of section 703 of the act, so long as [1] the recordkeeping requirement is limited, [2] clearly assists the efficient enforcement of the act, and [3] the burden of recordkeeping is not unreasonably onerous'' (60 FR 65096 at 65100 (*citing National Confectioners*, 569 F.2d at 693 n.9)).

The recordkeeping requirement in this rule satisfies the three criteria in *National Confectioners* for the agency to require records and have access to records. First, the requirement is limited to only manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle and to importers of record of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle. FDA has excluded all of the other persons who may be involved in the distribution of human food or cosmetics before they reach consumers but who do not manufacture or process the food.

Second, the recordkeeping requirement not only clearly assists the efficient enforcement of the act, but is critical to its enforcement because it is vital to determining compliance with the ban on prohibited cattle material. There is currently no test to detect reliably the presence of prohibited cattle material in human food and cosmetics. If FDA cannot require and access records demonstrating compliance, FDA may not be able to determine whether a human food or cosmetic contains cattle material that is prohibited. For example, without records, FDA may not be able to determine whether cattle material that may be specified risk material (e.g., brain or spinal cord) came from an animal that was less than 30 months old, whether the source animal for cattle material was inspected and passed, whether the source animal for cattle material was nonambulatory disabled, and whether tallow in a human food or cosmetic contains less than 0.15 percent insoluble impurities.

Under the IFR, failure of a manufacture or processor to operate in compliance with the ban on prohibited cattle materials renders a food or cosmetic adulterated as a matter of law. The introduction or delivery for introduction into interstate commerce of an adulterated food or cosmetic is a prohibited act under section 301(a) of the act (21 U.S.C. 331(a)), and the adulteration of any food or cosmetic in interstate commerce violates section 301(b) of the act (21 U.S.C. 331(b)). Thus, in order for us to determine whether a human food or cosmetic is adulterated and whether a manufacturer or processor has committed a prohibited act, we must have access to the manufacturer or processor's records.

Third, the burden of the recordkeeping requirement in this rule is not unreasonably onerous. The only records that must be retained are those sufficient to demonstrate that a human food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. First and foremost, FDA believes that it is only requiring records that a manufacturer or processor itself would need to keep to ensure its compliance with the rule. Just as there is no way for FDA to determine whether a product contains prohibited cattle material because there is currently no test to detect such material, there is no way for a manufacturer or processor to know without records. For example, without records, a manufacturer or processor of human food or cosmetics manufactured from, processed with, or otherwise containing, cattle material cannot determine whether cattle material that may be specified risk material (e.g., brain or spinal cord) came from an animal that was less than 30 months old, whether the source animal for cattle material was inspected and passed, whether the source animal for cattle material was nonambulatory disabled, and whether tallow in a human food or cosmetic contains less than 0.15 percent insoluble impurities.

Further, the rule does not dictate specific records but allows for covered manufacturers and processors to comply in the way that is least burdensome for them while demonstrating compliance. Also, many of the records that covered manufacturers and processors of human food may choose to retain are similar to those that are required by FDA's Bioterrorism Act recordkeeping rule. Finally, by allowing for efficient enforcement of the requirements that minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease, FDA's recordkeeping rule ''reflect[s] the objective of the [Federal Food, Drug, and Cosmetic] Act and carr[ies] out its mandate'' (*National Confectioners*, 569 F.2d at 694).

III. Summary of Requirements

The recordkeeping provisions of this rule apply to food and cosmetics covered by the IFR, including food additives, dietary supplements, and dietary ingredients.

As discussed in section II of this document, we have modified the codified section based on comments we received on the proposed rule. In this final rule, in §§ 189.5(c)(1) and 700.27(c)(1), 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. We intend to publish guidance that will describe in detail the records we recommend that manufacturers and processors maintain to demonstrate compliance with the ban on the use of prohibited cattle materials.

In §§ 189.5(c)(2) and 700.27(c)(2), we specify the period of time (2 years) that records must be retained. In §§ 189.5(c)(3) and 700.27(c)(3), we require that records be maintained at the manufacturing or processing establishment or at a reasonably accessible location. Sections 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. Sections 189.5(c)(5) and 700.27(c)(5) provide that records required by these sections and existing records relevant to compliance with these sections must be available to FDA for inspection and copying.

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 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 this 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.

Sections 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 part 11 (21 CFR part 11) in § 11.3(b)(6) are exempt from the requirements of part 11. Records that satisfy the requirements of this rulemaking, but that are also required under other applicable statutory provisions or regulations, remain subject to part 11.

IV. Regulatory Impact Analysis

A. Benefit-Cost Analysis

FDA has examined the economic implications of this final 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 final rule is a significant regulatory action because it raises novel policy issues; however, we have determined that this final rule is not an economically significant regulatory action.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA finds that this final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any 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 one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product (Ref 1). FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law No. 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 U.S.-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 final rule will not be a major rule for the purpose of congressional review.

1. Need for Regulation

As explained in this document, USDA's amended BSE IFR requires that SRMs, tissue from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, 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, as well as the tonsils and distal ileum of the small intestine of all cattle. USDA's BSE IFR requires that all of the prohibited materials be destroyed or sent to inedible rendering. This final rule implements recordkeeping for the provisions of the IFR on use of materials from cattle and responds to the same public health concerns. This final rule will not affect the incidence of BSE in cattle, which is addressed in other FDA regulations. This final rule will 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. Without the recordkeeping requirements in this final rule manufacturers and processors might not establish and maintain records to ensure that cattle material does not contain prohibited cattle materials, it may not be possible to determine whether cattle material that may be specified risk material (*e.g.*, brain or spinal cord) came from an animal that was less than 30 months old, it may not be possible to determine whether the source animal for cattle material was inspected and passed, and a product might contain MS beef without its presence being evident.

2. Final Rule Coverage

This final rule will require recordkeeping to ensure and document compliance with the provisions of the IFR (on use of materials from cattle) that prohibit the use of ''prohibited cattle materials.'' This final rule will require that manufacturers and processors of human foods and cosmetics that are manufactured from, processed with, or otherwise contain, cattle materials 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. Because we do not easily have access to records maintained at foreign establishments, we have included in this final rule a requirement that, when filing entry with U.S. Customs and Border Protection, importers of human food and cosmetics manufactured from, processed with, or otherwise containing, cattle material must affirm that the food or cosmetic was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the food or cosmetic was manufactured in accordance with this 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.

3. Comments Received on the Proposed Rule

(Comment) We received several comments that stated that FDA underestimated the economic impact of the proposed rule by omitting entire industries that would be subject to the rule. According to the comments, FDA had only estimated the costs of the rule to end-users of cattle material and had not considered the costs of the rule to those persons that produce intermediate

cattle-derived products. Specifically, manufacturers of collagen casings, intestinal casings, flavoring extracts, and gelatin are not appropriately accounted for in the proposed rule analysis.

(Response for gelatin) In the case of gelatin, FDA did estimate the impact of the proposed rule on food manufacturers of intermediate products that are from cattle-derived gelatin. Depending on the product, FDA had information on cattle-derived materials manufactured by intermediate producers (e.g., input suppliers to cosmetics manufacturers) or information on end products that contained cattle materials (e.g., foods). Whether our information was on intermediate manufacturers or end products, we estimated the impact of the rule on both the upstream and downstream facilities. FDA did not include estimates of bovine gelatin use in cosmetics in the analysis of the proposed rule. We have included these estimates in the final analysis.

(Response for small intestine) FDA did not estimate any costs, other than recordkeeping, for the requirement that the distal ileum be removed from the small intestine because costs other than recordkeeping are linked to the prohibition in FDA's IFR.

(Response for flavoring extracts) In the case of flavoring extracts, manufacturers and the buyers of flavoring extracts for use in food products were accounted for in the proposed rule. We assessed recordkeeping costs for the 32 facilities (out of 127 facilities) that we estimated were likely to manufacture flavoring extracts using cattle-derived materials and for the buyers of these flavoring extracts. FDA assumed three scenarios for sensitivity analyses: (1) Recordkeeping costs are borne entirely by the flavoring extract manufacturers as the input supplier, (2) recordkeeping costs are borne entirely by the manufacturers of products that use flavoring extracts as an ingredient in their products, and (3) recordkeeping costs are shared between the two types of firms.

(Response for collagen) FDA did not estimate the impacts of our proposed rule on collagen manufacturers or collagen casing manufacturers. This rule does not require recordkeeping for hide-derived collagen. Therefore we do not include the costs of recordkeeping to manufacturers who use hide-derived collagen. We do include costs for some collagen use in cosmetic manufacturing.

4. Costs and Benefits of the Final Rule

This final rule will 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 final rule will require that the manufacturer or processor retain records for 2 years from the date they were created. 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 and other records relevant to compliance for inspection and copying.

a. *Costs of final rule to domestic facilities.* FDA used establishment data from the FDA Small Business Model (which includes information on all establishments in a manufacturing sector regardless of size) (Ref. 2) 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 final rule; many may not. It is likely that some of the 132 establishments that produce fats and oils currently use tallow or tallow derivatives,[4] so FDA assumes that records will be required to be kept by only 75 percent of the facilities (99 of 132) in this establishment group. We assume that only 25 percent of the establishments from the remaining production sectors listed previously 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 research shows that 42 establishments with U.S. addresses supply cattle-derived ingredients that are used in cosmetics (Ref. 3). These cattle-derived ingredients include bovine serum albumin, cholesterol and cholesterol compounds, fibronectin, sphingolipids, spleen extract, tallow, gelatin, and keratin and keratin compounds. From FDA's dietary supplement database (Ref. 4), we are able to tell that there are about 131 U.S.-based 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.

Recordkeeping costs to domestic facilities. USDA's BSE rule requires that 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 requirements will reduce, but likely not eliminate, the startup costs of recordkeeping required by this final rule. We do not expect the USDA rule to completely eliminate start-up costs to recordkeeping for this rule because the beef products under USDA's jurisdiction differ from the food products under FDA's jurisdiction. To the extent that manufacturers of products containing cattle-derived materials produce a variety of food products, some of which are under USDA jurisdiction and some of which are under FDA jurisdiction, the following estimates of recordkeeping costs (for foods only) are likely an over estimate.

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 assumed to be negligible. Current business practices already dictate that records are kept for at least 1 year for tax purposes and product liability purposes. FDA has found that records are usually kept much longer for internal business purposes; therefore, in most cases the marginal private benefits to facilities from retaining records for a second year are apparently greater than the private marginal costs, so they keep most records. Because records retention is already standard practice in many cases, we assume that the additional retention costs associated with this final

[4] Tallow derivatives are exempt from recordkeeping.

rule are approximately zero. The rule provides no specific time period for providing records, except for importers of record, who are given 5 days. In research conducted for FDA's Bioterrorism Act recordkeeping rule (69 FR 71562, December 9, 2004), FDA found that record request costs are not a significant burden under that rule's requirement to submit records to FDA within 24 hours of a request. Therefore, we assume the cost to provide records to FDA under the requirements of this final rule is approximately zero.

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 or created, and the training required for personnel to learn how to file and maintain those records. As part of current business practices, personnel are familiar with recordkeeping. Therefore, the requirement to maintain additional records will be learned quickly. This training burden estimated for recordkeeping in this final rule is consistent with the recordkeeping training burden in the analysis for the Bioterrorism Act recordkeeping rule and the records maintenance burden in the analysis of the juice hazard analysis critical control points (HACCP) rule (66 FR 6137–6202). Consistent with the analysis conducted for the Bioterrorism Act recordkeeping rule, FDA assumes an hourly cost of an administrative worker, $25.10 per hour, which includes overhead 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. 5). 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 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 product containing cattle-derived material.

Unlike for the analysis of the Bioterrorism Act recordkeeping rule (69 FR 71562, December 9, 2004), we do not have direct information on all the facilities covered; we do not have data on all the intermediate cattle material suppliers or finished product manufacturers that make use of cattle-derived material for human food and cosmetics under FDA jurisdiction. Using information on the number of human food manufacturers and cosmetic ingredient suppliers that may use cattle-derived ingredients subject to this final rule, we can account for the total shared records costs by assuming that each food manufacturer or processor in table 1 of this document procures ingredients from one upstream input supplier for particular cattle-derived ingredients. Even if multiple input suppliers are used by the manufacturing facility, or an input supplier is used by multiple manufacturing facilities, the marginal record setup costs would decrease for additional suppliers or additional manufacturers. Once a facility has designed the required records, it is less costly to generate records for additional input suppliers or additional end product manufacturers. Table 1 of this document shows estimated set-up costs for U.S. facilities. Dietary supplement facilities listed represent end product manufacturers of dietary supplements that contain cattle-derived material; cosmetics facilities are represented by intermediate cattle-derived ingredients used in cosmetics products from domestic cosmetic input suppliers.

TABLE 1.—FIRST-YEAR RECORDS COSTS FOR DOMESTIC FACILITIES

Type of product using cattle material	Number of facilities estimated to use cattle materials	Costs per facility for designing records	Costs per facility for training (⅓ hour × $25.10 per hour)	Total setup costs
Canned soups and stews	10	$1,785	$8.37	$17,934
Fats and oils	99	1,785	8.37	177,544
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
Small intestine-derived casings	47	1,785	8.37	84,288
Dietary supplements	131	1,785	8.37	234,931
Cosmetics	42	1,785	8.37	75,322
Color additives	0	1,785	8.37	.....
Total	697	1,785	8.37	1,249,978
Startup Costs Annualized over 10 years (7%)				177,969
Startup Costs Annualized over 10 years (3%)				146,536

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 recordkeeping rule (69 FR 71562, December 9, 2004). In that analysis we estimated that 30 minutes per week would be needed 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 final rule will cover only a small fraction of all ingredients used in food and cosmetic manufacturing 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 average burden per facility to be about one-half of the burden estimated for the Bioterrorism Act recordkeeping rule: 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 containing cattle-derived ingredients). For facilities using records that are renewable annually, the time pattern of the burden may be different from the assumed 15 minutes per week. We are, however, unable to quantify by how much time, if any, the annual burden will fall for those facilities using that option.

In addition to the recurring costs to domestic firms in the industry, as new firms enter the industry they will bear one-time costs. 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 the annual one-time costs for new domestic firms entering the industry to be 10 percent of the one-time costs of existing domestic firms estimated in table 1 of this document.

Table 2 of this document shows the recurring recordkeeping costs that would be incurred by food and cosmetics input suppliers and manufacturers to comply with this final rule. As stated earlier, information on food producing facilities in table 2 represents U.S. facilities; dietary supplement facilities listed represent end product manufacturers of dietary supplements that contain cattle-derived material and cosmetics facilities are represented by intermediate cattle-derived ingredients used in cosmetics products from domestic cosmetic input suppliers.

TABLE 2.—RECURRING ANNUAL RECORDS COSTS FOR DOMESTIC FACILITIES

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/hour)	Total recurring annual costs
Canned soups and stews	10	$326.30	$3,263
Fats and oils	99	326.30	32,304
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
Small intestine-derived casings	47	326.30	15,336
Dietary supplements	131	326.30	42,745
Cosmetics	42	326.30	13,705
Color additives	0	.....	.....
Total recurring costs for existing firms	697	326.30	227,430
One-time costs for new firms			124,998
Total annual costs			352,428
Total costs of recordkeeping for domestic firms (annualized startup costs (7%) + annual costs)			530,397
Total costs of recordkeeping for domestic firms (annualized startup costs (3%) + annual costs)			498,964

b. *Costs of final rule to importers.* This final rule requires that, when filing entry with U.S. Customs and Border Protection, importers of record of human food and cosmetics that are manufactured from, processed with, or otherwise contain, cattle material must affirm that the 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 this rule. 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.

The affirmation that foods or cosmetics are manufactured from, processed with, or otherwise contain, cattle material and are manufactured in accordance with the rule will be made by the importer of record to FDA through the Agency's Operational and Administrative System for Import Support (OASIS). Table 3, using OASIS data from fiscal year 2004, shows 2,195,000 entry lines of food and cosmetics for the product codes that FDA expects may contain products with cattle materials entered the U.S.; 0 to

100 percent of these imported product lines will be for products that actually do contain cattle material and require affirmation. We use the information in table 3 to generate recordkeeping costs to importers (in tables 4 and 5) whose products actually do contain cattle-derived materials.

TABLE 3.—ANNUAL LINES PER FDA INDUSTRY PRODUCT CODE FOR WHICH IMPORTERS MUST VERIFY USE OF CATTLE-DERIVED MATERIALS [1]

Industry description	FDA industry product code	Fiscal year 2004 line count
Bakery products, dough, mix, and icing	03	700,222
Macaroni and noodle products	04	24,011
Milk, butter, and dried milk products	09	12,228
Cheese and cheese products	12	2,712
Ice cream products	13	2,698
Filled milk and imitation milk products	14	990
Fishery and seafood products	16	4,775
Meat, meat products and poultry	17	5,322
Vegetable protein products	18	16,702
Fruit and fruit products	20	16,410
Fruit and fruit products	21	13,112
Fruit and fruit products	22	1,532
Nuts and edible seeds	23	24,216
Vegetables and vegetable products	24	323,004
Vegetables and vegetable products	25	321,032
Vegetable oils	26	1,532
Dressings and condiments	27	16,386
Spices, flavors, and salts	28	203
Candy (except chocolate candy), chewing gum	33	275,733
Chocolate and cocoa products	34	126,719
Gelatin, rennet, pudding mix, pie filling	35	22,485
Multiple food dinners, gravy, and sauces	37	82,105
Soup	38	37,923
Prepared salad products	39	13,357
Baby food products	40	576
Dietary convenience foods and meal replacements	41	18,189
Food additives (human use)	45	23,877
Food additives (human use)	46	14,699
Miscellaneous food related items	52	1,501
Cosmetics	53	27,867
Vitamins, minerals, proteins, unconventional dietary specialties	54	63,184
Total annual lines	.....	2,195,302

[1] Note that not every import within each two-digit FDA product code will be required to make an affirmation of bovine materials in their products.

Recordkeeping costs to foreign facilities. Facilities producing products required to give affirmation on import into the U.S. whose products actually do contain cattle-derived materials will have to create and maintain records of cattle-derived materials used in product production. Therefore, a certain percentage of the firms whose products are listed in Table 3 above will have to incur startup and recurring recordkeeping costs, as domestic facilities do, to comply with the recordkeeping requirements of this final rule.

We do not expect many imported food products under FDA jurisdiction will actually contain cattle-derived materials. Table 4 below revises table 3 to only include the percentage (10 percent) of certain imported products likely to contain cattle materials and whose manufacturing firms will keep records. We do not include the categories of food from table 3 where affirmation could be required but it is not likely that products from that category actually contain cattle-derived materials. We estimate only 10 percent of lines rather than 25 percent or 75 percent as we did for domestic products because import category codes tend to be broader in scope than the categories we used for determining the number of domestic facilities that produced products using cattle-derived materials.

To estimate the number of foreign firms associated with the 10 percent of line entries listed in table 4, we take *all foreign* firms registered in the Food Facilities Registration Database as of the end of the fiscal year 2004 (approximately 125,000) and divide that number of firms by *all imported food entry lines* for fiscal year 2004 (7,486,650).[5] The result is a multiplier (0.0167) that we apply to entry lines to estimate the average number of firms by product category that exported food or cosmetics to the U.S. in fiscal year 2004, and whose products actually contained cattle-derived materials for which records would need to be kept.

Table 4 below shows that about 916 foreign firms will need to keep records of cattle-derived materials. The startup costs to keeping these records will be about $1.6 million. Since we do not have good information on the number of firms that actually produce and export products that contain cattle-derived materials to the U.S., the costs in table 4 below may overestimate recordkeeping costs to firms in some product categories and may

[5] Cosmetic lines have been subtracted from the line total because cosmetics manufacturers do not have to register.

underestimate recordkeeping costs to firms in other product categories.

TABLE 4.—FIRST YEAR RECORDS COSTS FOR FOREIGN FACILITIES

Industry description	Fiscal year 2004 line count	10 percent of lines	Number of facilities	Total setup costs ($1,793 per firm)
Milk, butter, and dried milk products	12,228	1,223	20	$36,614
Ice cream products	2,698	270	5	8,079
Meat, meat products and poultry	5,322	532	9	15,936
Vegetable oils	1,532	153	3	4,587
Dressings and condiments	16,386	1,639	27	49,065
Spices, flavors, and salts	203	20	0	0
Candy (except chocolate candy), chewing gum	275,733	27,5723	460	825,630
Gelatin, rennet, pudding mix, pie filling	22,485	2,249	38	67,327
Multiple food dinners, gravy, and sauces	82,105	8,211	137	245,848
Soup	37,923	3,792	63	113,553
Baby food products	576	58	1	1,725
Cosmetics	27,867	2,787	47	83,442
Vitamins, minerals, proteins, unconventional dietary specialties	63,184	6,318	106	189,192
Total			916	1,640,999
Startup Costs Annualized over 10 years (7%)				233,641
Startup Costs Annualized over 10 years (3%)				192,375

The recurring recordkeeping cost to importers whose products contain cattle-derived materials is the cost of ensuring that appropriate records document the absence of prohibited cattle materials in human food and cosmetics. We use the same method and rationale to calculate the recurring recordkeeping cost burden to foreign facilities that we used for domestic facilities.

In addition to the recurring costs to foreign firms in the industry, as new firms enter the industry they will bear one-time costs. 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 the annual one-time costs for new foreign firms entering the industry to be 10 percent of the one-time costs of existing foreign firms estimated in table 4.

Also shown in table 5 are the annual costs to importers to affirm that the human food or cosmetics that they are importing do contain cattle material and are in compliance with this rule. Importers of approximately 54,825 lines of food and cosmetics are expected to affirm annually that the products they are importing contain cattle materials. 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. Using an importer hourly wage cost of $46.58 (Ref. 6), which includes overhead, FDA estimates that importer affirmation will take about two minutes per line at a cost of $1.55 per affirmation for total annual affirmation costs of $84,979.

TABLE 5.—RECURRING ANNUAL RECORDS COSTS FOR FOREIGN FACILITIES

Industry description	Fiscal year 2004 line count	10 percent of lines	Number of facilities	Total recurring annual costs ($326.30 per firm)
Milk, butter, and dried milk products	12,228	1,223	20	$6,663
Ice cream products	2,698	270	5	1,470
Meat, meat products and poultry	5,322	532	9	2,900
Vegetable oils	1,532	153	3	835
Dressings and condiments	16,386	1,639	27	8,929
Spices, flavors, and salts	203	20	0	111
Candy (except chocolate candy), chewing gum	275,733	27,573	460	150,253
Gelatin, rennet, pudding mix, pie filling	22,485	2,249	38	12,253
Multiple food dinners, gravy, and sauces	82,105	8,211	137	44,741
Soup	37,923	3,792	63	20,665
Baby food products	576	58	1	314
Cosmetics	27,867	2,787	47	15,185
Vitamins, minerals, proteins, unconventional dietary specialties	63,184	6,318	106	34,430
Total		54,825	916	298,638
Total Annual Importer Affirmation Costs ($1.55 per line for 54,825 lines)				84,979
One-time costs for new firms				164,100
Total annual costs				547,717
Total costs of recordkeeping for foreign firms (annualized startup costs (7%) + annual costs				781,358
Total costs of recordkeeping for foreign firms (annualized startup costs (3%) + annual costs)				740,092

c. *Benefits of the final rule.* The benefits of this final rule are derived from the benefits of the interim final rule on use of material from cattle, 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 banning prohibited cattle materials for use in foods and cosmetics would be: (baseline annual cases of vCJD − annual cases of vCJD under FDA IFR on use of materials from cattle) × (value of preventing a case of vCJD).

An alternative way to characterize benefits is:

(reduction in annual cases in vCJD under FDA IFR on use of materials from cattle) × (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 IFR on use of materials from cattle and this final rule will 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 rulemaking 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 may be similar. FDA uses the concept of the Value of a Statistical Life (VSL) in order to describe the value of preventing a case of vCJD. This term refers to the sum of risk reductions expected in a population exposed to small changes in risk. It has no application to identifiable individuals or large reductions in risk. Most recent studies suggest values ranging from about $1 million to $10 million. In recent rulemakings, we have used $5 million and $6.5 million as the value of a statistical life, and we believe it is reasonable to use a similar VSL to value the cases of vCJD avoided.

As discussed in FDA's IFR on use of materials from cattle, the Harvard-Tuskegee study has stated that a ban on SRMs, 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 88 percent and potential human exposure to infectivity in meat and meat products by 95 percent (Ref. 7). The FDA IFR on use of materials from cattle, in conjunction with USDA's BSE IFR, will help achieve this reduction in potential human exposure. FDA's IFR on use of materials from cattle will also reduce potential human exposure to BSE infectivity in other human food not covered by the Harvard-Tuskegee study and from cosmetics. This final rule will help ensure that the provisions of the IFR on use of materials from cattle are carried out. For example, this final 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 the final rule.* For this final rule, the costs are to set up and then to maintain a recordkeeping system to document that cattle-derived ingredients used in FDA-regulated food and cosmetics do not contain prohibited cattle material. The first year costs of this final rule are about $1.2 million to domestic facilities and about $1.6 million to foreign facilities. The annual costs of this final rule are about $352 thousand in recordkeeping costs to domestic facilities, $548 thousand in recordkeeping costs to foreign facilities. Costs of this final rule annualized at 7 percent over 10 years are about $530 thousand to domestic facilities and $781 thousand to foreign facilities; costs annualized at 3 percent over 10 years are $500 thousand to domestic facilities and $740 thousand to foreign facilities.

The benefits of this final rule are to ensure that cattle-derived products that may possibly be contaminated with BSE do not find their way into food and cosmetic products, thus further reducing the risk of vCJD to humans.

TABLE 6.—SUMMARY OF COSTS AND BENEFITS

	Number of facilities	Start-up recordkeeping costs	Recurring recordkeeping costs	Total costs annualized at 7% for 10 years	Total costs annualized at 3% for 10 years
Costs to Domestic Facilities	697	$1,249,978	$352,428	$530,397	$498,964
Costs to Foreign Facilities	916	$1,640,999	$547,717	$781,358	740,092
Total	1613	$2,890,977	$900,145	$1,311,755	1,239,056

Benefits—To ensure that cattle-derived products that may possibly be contaminated with BSE do not find their way into food and cosmetic products, thus further reducing the risk of vCJD to humans.

B. Regulatory Flexibility Analysis

FDA has examined the economic implications of this final 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 final rule will have a significant economic impact on a substantial number of small entities.

First-year costs of this final rule are about $1,800 per facility pair, with this cost divided between the upstream facility (ingredient input supplier) 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 final 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 final rule are about $326 per facility relationship, which may be borne by only one facility or may be shared between facilities.

Using FDA's Small Business Model, we can estimate, when recordkeeping costs are shared and when they are not shared, the number of facilities that may go out of business as a result of this final rule. Table 7 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 (fewer than 20 employees) may be affected by having to comply with this final rule. 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 (fewer than 20 employees) may have trouble complying with this final rule and staying in business. The option to use a continuing letter of guarantee, however, may introduce sufficient flexibility to reduce the burden on some small facilities, which may reduce the number of very small facilities that will have trouble staying in business. Facilities with 20 to 499 employees and facilities with at least 500 employees that must comply with this final rule are not in danger of having to stop operating as a result of the final rule.

TABLE 7.—POTENTIAL FOR DOMESTIC 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
Fats and oils	99	900	0
Fats and oils	99	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
Ice cream	113	1,800	1
Small intestine-derived casings	47	900	0
Small intestine-derived casings	47	1,800	0
Dietary supplements	131	900	1
Dietary supplements	131	1,800	2
Cosmetics	42	900	0
Cosmetics	42	1,800	0

We would expect the potential for small business shutdown would be similar for foreign firms that continue to import their products with cattle-derived materials into the United States. It is possible that some foreign firms would choose to cease doing business with the United States if the recordkeeping requirements of this rule are too burdensome.

V. Paperwork Reduction Act Analysis

This final rule contains information collection provisions 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 follows with an estimate of the annual recordkeeping 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.

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

Description: This final rule will 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 final rule implements recordkeeping for the provisions of FDA's interim final rule entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics.'' This final rule will 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 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 that may be specified risk material (*e.g.*, brain or spinal cord) came from an animal that was less than 30 months old, (2) whether the source animal for cattle material was inspected and passed, (3) whether the source animal for cattle material was nonambulatory disabled, and (4) whether tallow in a human food or cosmetic contains less than 0.15 percent insoluble impurities. Under the final rule, manufacturers and processors must retain records for 2 years at the manufacturing or processing establishment or another reasonably accessible location.

A. Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

TABLE 8.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number 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.

B. 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.

C. 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 × 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 (Ref. 5). 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 8 of this document shows the total hour burden from training and records design to be 44.33 hours per facility × 697 recordkeepers = 30,898 hours for the year.

D. 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 × 697 = 9,061 hours, as shown in row 2 of table 8 of this document.

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 8 of this document 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 × 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 8 of this document) the annual one-time burden for new firms entering the industry to be 10 percent of the one-time burden of existing firms estimated.

E. Capital Cost and Operating and Maintenance Cost Burden

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 (Ref. 5). 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 × 697 = $480,930. These one time costs are shown in row 1 of table 5 of this document. 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 8.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final 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, the agency concludes that the final 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.

VII. References

The following references have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Department of Commerce, Bureau of Economic Analysis, National Economic Accounts, *http://www.bea.gov/bea/dn.1.htm.*

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

3. CTFA International Buyer's Guide, produced by the Cosmetic, Toiletry, and Fragrance Association (CTFA), *http://www.ctfa-buyersguide.org.*

4. FDA Database of Dietary Supplement Products that Contain Animal Ingredients (DSPD–A), RTI International, September 2002.

5. FDA Labeling Cost Model, Final Report, RTI International, January 2003.

6. May 2004 Occupational Employment and Wage Estimates, National Cross-Industry estimates, U.S. Department of Labor, Bureau of Labor Statistics, accessed October 2, 2006, *http://www.bls.gov/oes/oes_dl.htm.*

7. Harvard Center for Risk Analysis, Harvard School of Public Health, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' accessed online at *http://www.hcra.harvard.edu/pdf/madcow.pdf,* 2003.

List of Subjects

21 CFR Part 189

Food additives, Food packaging, Reporting and recordkeeping requirements.

21 CFR Part 700

Cosmetics, Packaging and containers, Reporting and recordkeeping requirements.

■ 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 amends 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) *Records.* (1) Manufacturers and processors of a 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 they 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 section and existing records relevant to compliance with this section must be available to FDA for inspection and copying.

(6) When filing entry with U.S. Customs and Border Protection, the importer of record of a human food manufactured from, processed with, or otherwise containing, cattle material must affirm that the food was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the food was manufactured in accordance with this section. If a human food 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 food is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material.

(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 in cosmetic products.

* * * * *

(c) *Records.* (1) 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 they 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 section and existing records relevant to compliance with this section must be available to FDA for inspection and copying.

(6) When filing entry with U.S. Customs and Border Protection, the importer of record of a cosmetic manufactured from, processed with, or otherwise containing, cattle material must affirm that the cosmetic was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the cosmetic was manufactured in accordance with this section. If a 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 cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material.

(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: October 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–16830 Filed 10–10–06; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9289]

RIN 1545–BD48

Treatment of Disregarded Entities Under Section 752

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations under section 752 for taking into account certain obligations of a business entity that is disregarded as separate from its owner under section 856(i) or section 1361(b)(3) of the Internal Revenue Code, or §§ 301.7701–1 through 301.7701–3 of the Procedure and Administration Regulations. These final regulations clarify the existing regulations concerning when a partner may be treated as bearing the economic risk of loss for a partnership liability based upon an obligation of a disregarded entity. The rules affect partnerships and their partners.

DATES: *Effective Date:* These regulations are effective on October 11, 2006.

Applicability Date: These regulations generally are applicable for liabilities incurred or assumed by a partnership on or after October 11, 2006.

FOR FURTHER INFORMATION CONTACT: Charlotte Chyr, 202–622–3070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1905. Response to this collection of information is mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection of information displays a valid control number.

The estimated annual burden per respondent varies from 6 minutes to 4 hours, depending on individual circumstances, with an estimated average of 2 hours. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, *Attn:* IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books and records relating to these collections of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by 26 U.S.C. 6103.

Background

On August 12, 2004, the IRS and the Treasury Department issued proposed regulations under section 752 providing rules for taking into account certain obligations of disregarded entities (69 FR 49832). Comments were received in response to the notice of proposed rulemaking, and a public hearing was scheduled. However, the public hearing was later cancelled when no one requested to speak. After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury decision.

Summary of Comments and Explanation of Provisions

1. Net Value Approach In General

The proposed regulations provide that a payment obligation under § 1.752–2(b)(1) (§ 1.752–2(b)(1) payment obligation) of a disregarded entity for which a partner is treated as bearing the economic risk of loss is taken into account only to the extent of the net value of the disregarded entity. Certain commentators disagreed with the approach taken in the proposed regulations, arguing that the regulations will result in inconsistent treatment of similar economic situations and unwarranted complexity.

Some commentators argued that the presumption of deemed satisfaction of § 1.752–2(b)(1) payment obligations of partners and related persons that is provided in § 1.752–2(b)(6) (presumption of deemed satisfaction) should be applied to disregarded entities that have § 1.752–2(b)(1) payment obligations. Other commentators argued that the presumption of deemed satisfaction should apply only to certain disregarded entities, such as disregarded entities that comprise substantially all of the owner's assets, or disregarded entities that hold active trades or businesses.

The IRS and the Treasury Department believe that applying the presumption of deemed satisfaction to a disregarded entity that shields the federal tax partner from liability for the entity's obligations would, in many cases, cause partnership liabilities that are economically indistinguishable from nonrecourse liabilities to be classified as recourse for purposes of section 752. Applying the presumption of deemed satisfaction to disregarded entities would distort the allocation of partnership liabilities in those cases. Accordingly, these comments are not adopted in the final regulations.

One commentator suggested that § 1.752–2 be amended to provide that, in addition to statutory and contractual obligations, statutory and contractual limitations should be taken into account in determining a partner's economic risk of loss. The IRS and the Treasury Department believe that such limitations are already taken into account under § 1.752–2(b)(3). As a result, the comment is not adopted.

Another commentator suggested that the goal of the proposed regulation could be better achieved by adding an example to the current anti-abuse rule in § 1.752–2(j) (or by publishing a revenue ruling) to illustrate a situation under which a partner's § 1.752–2(b)(1) payment obligation is limited because the partner holds its interest in a partnership through a disregarded entity with a principal purpose to eliminate the partner's economic risk of loss with respect to the partnership's liabilities. The IRS and the Treasury Department agree that, in certain circumstances, the current anti-abuse rule under section 752 prevents allocation of partnership liabilities to a partner that is a disregarded entity. However, if a partner holds a partnership interest through a disregarded entity, and only the assets of the disregarded entity are available to satisfy § 1.752–2(b)(1) payment obligations undertaken by the disregarded entity, the IRS and the Treasury Department believe that a partner should be treated as bearing the economic risk of loss for a partnership liability only to the extent of the net value of a disregarded entity's assets, whether or not the principal purpose of the arrangement is to limit the partner's economic risk of loss. As a result, the comment is not adopted.