materials and decide whether an applicant is a ''small business'' within the meaning of MDUFMA.

FDA Form 3602A— For Foreign Small Business Applicants

The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly-lower fee when a medical device user fee must be paid.

Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected.

In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification,'' must:

- Be in English;
- Be from the national taxing authority of the country in which the business is headquartered;
- Provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars;
- Provide the dates during which the reported receipts or sales were collected; and
- Bear the official seal of the national taxing authority.

Both FDA Forms 3602 and 3602A are available in the guidance document, ''Guidance for Industry, FDA and Foreign Governments: FY 2010 MDUFMA Small Business Qualification and Certification'' *, available on the Internet at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM179257.pdf*. This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2010.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000
3602A Sections I and II	340	1	340	1	340
3602A Section III	33	7	231	1	231
TOTALS					3,571

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

The FDA Form 3602 burden is based on the number of applications received in the last 3 years. FDA believes most entities that submit FDA Form 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with FDA Form 3602A, FDA believes each business will require 1 hour to complete Sections I and II. FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification, since there is a different tax verification process by each country's National Taxing Authority.

The information collection for FDA Form 3602 is currently approved under OMB control number 0910–0508. The information collection for FDA Form 3602A is currently approved under OMB control number 0910–0613. With this request for approval, FDA is requesting to consolidate OMB approvals 0910–0508 and 0910–0613 into one information collection using the OMB control number 0910–0508.

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25538 Filed 10–22–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0505]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements of FDA's regulations that 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.

DATES: Submit written or electronic comments on the collection of information by December 22, 2009.

ADDRESSES: Submit electronic comments on the collection of

information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle—21 CFR 189.5(c) and 700.27(c) (OMB Control Number 0910–0597—Extension)

Sections 189.5(c) and 700.27(c) (21 CFR 189.5(c) and 700.27(c)) of FDA's regulations set forth the requirements for recordkeeping and records access for FDA-regulated human food, including dietary supplements, and cosmetics that are manufactured from, processed with, or otherwise contain, material derived from cattle. FDA issued these recordkeeping regulations under the adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), (a)(5), 601(c), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)). Under section 701(a) of the act, FDA is authorized to issue regulations for the act's efficient enforcement. With regard to records concerning imported human food and cosmetics, FDA relied on its authority under sections 801(a) and 701(b) of the act (21 U.S.C. 381(a)). Section 801(a) of the act provides requirements with regard to imported food and cosmetics and provides for refusal of admission into the United States of human food and cosmetics that appear to be adulterated. Section 701(b) of the act authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

These requirements are necessary because, once materials are separated from an animal, it may not be possible without records to know the following: (1) Whether cattle material may contain specified risk materials (SRMs). SRMs include brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia from animals less than 30 months old and tonsils and distal ileum of the small intestine from all animals of all ages; (2) whether the source animal for cattle material was inspected and passed; (3) whether the source animal for cattle material was nonambulatory disabled or mechanically separated beef; and (4) whether tallow in a human food or cosmetic contains less than 0.15 percent insoluble impurities.

These regulations implement recordkeeping for the provisions of FDA's interim final rule entitled ''Use of Materials Derived From Cattle in Human Food and Cosmetics'' (the IFR) (69 FR 42256, July 14, 2004). FDA's regulations in §§ 189.5(c) and 700.27(c) require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle establish and maintain records sufficient to demonstrate that the human food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. These records must be retained for 2 years at the manufacturing or processing establishment or at a reasonably accessible location. Maintenance of electronic records is acceptable and electronic records are considered to be reasonably accessible if they are accessible from an onsite location. Records required by these sections and existing records relevant to compliance with these sections must be available to FDA for inspection and copying. Existing records may be used if they contain all of the required information and are retained for the required time period.

Because we do not easily have access to records maintained at foreign establishments, FDA regulations in §§ 189.5(c)(6) and 700.27(c)(6), respectively, require that when filing for entry with U.S. Customs and Border Protection, the importer of record of a human food or cosmetic manufactured from, processed with, or otherwise containing, cattle material must affirm that the human food or cosmetic was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the human food or cosmetic was manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. In addition, if a human food or cosmetic is manufactured from, processed with, or otherwise contains, cattle material, then the importer of record must, if requested, provide within 5 business days records sufficient to demonstrate that the human food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material.

Description of Respondents: Respondents to this information collection include manufacturers, processors, and importers of FDA-regulated human food, including dietary supplements, and cosmetics that are manufactured from, processed with, or otherwise contain, material derived from cattle.

FDA estimates the burden of this collection of information as follows:

This estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled,

''Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle,'' published in the **Federal Register** of October 11, 2006 (71 FR 59653 at 59667).

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total
Domestic Facilities 189.5(c) and 700.27(c)	697	52	36,244	0.25	9,061
Foreign Facilities 189.5(c) and 700.27(c)	916	52	47,632	0.25	11,908
Total					20,969

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

FDA estimates that there are 697 domestic facility relationships (71 FR 59653 at 59667), and 916 foreign facility relationships (71 FR 59653 at 59663), consisting of the following facilities: An input supplier of cattle-derived materials that requires records (the upstream facility) and a purchaser of cattle-derived materials requiring documentation—this may be a human food or cosmetic manufacturer or processor. The recordkeeping burden of FDA's regulations in §§ 189.5(c) and 700.27(c) is the burden of sending, verifying, and storing documents regarding shipments of cattle material that is to be used in human food and cosmetics. In this estimate of the recordkeeping burden, we treat these recordkeeping activities as shared activities between the upstream and downstream facilities. It is in the best interests of both facilities in the relationship to share the burden necessary to comply with the regulations; therefore, we estimate the time burden of developing these records as a joint task between the two facilities. Thus, we estimate that this recordkeeping burden will be about 15 minutes per week, or 13 hours per year (71 FR 59653 at 59667), and we assume that the recordkeeping burden will be shared between 2 entities (i.e. the ingredient supplier and the manufacturer of finished products). Therefore, the total recordkeeping burden for domestic facilities is estimated to be 13 hours x 697 = 9,061 hours, and the total recordkeeping burden for foreign facilities is estimated to be 13 hours x 916 = 11,908 hours, as shown in table 1 of this document.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
189.5(c)(6) and 700.27(c)(6)	54,825	1	54,825	0.033	1,809

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

FDA's regulations in §§ 189.5(c)(6) and 700.27(c)(6) impose a reporting burden on importers of human food and cosmetics that are manufactured from, processed with, or otherwise contain, cattle material. Importers of these products must affirm that the food or cosmetic is manufactured from, processed with, or does not otherwise contain, prohibited cattle materials and must affirm that the human food or cosmetic was manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. The affirmation is made by the importer of record to FDA through the agency's Operational and Administrative System for Import Support. Affirmation by importers is expected to take approximately 2 minutes per entry line. Table 2 of this document shows that 54,825 lines of food and cosmetics that likely contain cattle materials are imported annually (71 FR 59653 at 59667). The annual reporting burden of affirming whether import entry lines contain cattle-derived materials is estimated to take 1,809 hours annually (54,825 lines x 2 minutes per line).

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–0789]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Program Effectiveness Evaluation of Workplace Intervention for Intimate Partner Violence (IPV)—[OMB# 0920–0789] [exp. 12/31/09]—Extension—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Intimate partner violence (IPV) affects a substantial number of Americans, and there has recently been increasing recognition of the impact it has on the workplace. In addition to direct impacts (batterers often stalk or even attack IPV