TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Total					20,969

[1] There are no capital costs 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 two entities (i.e., the ingredient supplier and the manufacturer of finished products). Therefore, the total recordkeeping burden for domestic facilities is estimated to be 13 hours 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 2.—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 costs 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 (OASIS). Affirmation by importers is expected to take approximately 2 minutes per entry line. Table 2 of this document shows that 54,825 lines of food and cosmetics that likely contain cattle materials are imported annually (71 FR 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: January 20, 2010.

David Dorsey

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1436 Filed 1–25–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0221]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 25, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0331. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93 (OMB Control Number 0910–0331—Extension)

Section 403(r)(6) of the act (21 U.S.C. 343(r)(6)) requires that the agency be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in

section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes the following items: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The agency established § 101.93 (21 CFR 101.93) as the procedural regulation for this program. Section 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in order to meet the requirements of section 403 of the act.

In the **Federal Register** of June 2, 2009 (74 FR 26406), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two letters in response, each containing one or more comments. One of these letters was received several months after the close of the comment period. The comments that were timely filed were outside the scope of the comment request.

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

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
101.93	2,200	1	2,200	0.75	1,650

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

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) statements on labels or in labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. FDA estimates that, each year, approximately 2,200 firms will submit the information required by section 403 of the act. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a communication to FDA, for a total of 1,650 hours (2,200 x 0.75). This estimate is based on the average number of notification submissions received by the agency in the preceding 2 years.

Dated: January 20, 2010.

David Dorsey

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1435 Filed 1–25–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Next Series of Tobacco Use Supplements to the Current Population Survey (TUS–CPS) (NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 6, 2009, (Vol. 74, No. 214, pp. 57496–97) and allowed 60 days for public comment. One request for information was received on November 6, 2009. A copy of the 2010–2011 TUS–CPS was e-mailed to the requestor reiterating our data collection plans as stated in the 60-day **Federal Register** Notice. Another comment was received on December 16, 2009 complimenting our inclusion in the 2010–2011 TUS–CPS of critically needed information on details about the types of cigars (especially small cigars) used by smokers and new and valuable information on menthol cigarette smoking. We thanked the requestor for the endorsement and agreed that we thought that was valuable and timely as well and that is why we have included the information in the proposed data collection. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Next Series of Tobacco Use Supplements to the Current Population Survey (TUS–CPS) (NCI). *Type of information request:* REINSTATEMENT WITH CHANGE of OMB #0925–0368, Expiration 4/30/2009. *Need and Use of Information Collection:* The 2010–2011 Tobacco Use Supplement to the Current Population Survey conducted by the Census Bureau will collect data from the U.S. civilian non-institutionalized population on smoking, other tobacco use, and attempts at cessation; policy information such as home and workplace smoking policies; health professional advice to stop smoking; and changes in smoking norms and attitudes. The TUS–CPS will be and has been in the past a key source of national, State, and some local-level data on these topics in U.S. households because it uses a large, nationally representative sample. This survey is part of a continuing series of surveys (OMB #0925–0368) that were sponsored by NCI and has been administered triennially as part of the U.S. Census Bureau's and the Bureau of Labor Statistics CPS. The TUS–CPS has been fielded since 1992, most recently in 2006–07, and its data are available for public use. Government agencies, other researchers and the public can use the data to monitor progress in the control