

“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<sup>1</sup>

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

<sup>1</sup> 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<sup>1</sup>

| 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       |

<sup>1</sup> 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.*

[FR Doc. E9–25537 Filed 10–22–09; 8:45 am]

**BILLING CODE 4160–01–S**

## 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](mailto: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

victims at their place of work), IPV has indirect impacts on the workplace environment through lost productivity due to medical leave, absenteeism, and fear and distraction on the part of victims and coworkers. The Centers for Disease Control and Prevention (CDC) contracted with RTI International (RTI) to evaluate an ongoing workplace IPV prevention program being implemented at a national corporation. The purpose of the proposed evaluation is to document in detail the workplace IPV prevention activities delivered by the company, to determine the impact of these activities on short-term and long-term outcomes, and to determine the cost-effectiveness of the program. All managers at the corporate office of the corporation have been screened to assess training experiences. More in-

depth surveys were conducted with managers who had not completed the corporation's IPV training. We have surveyed managers at baseline, and 6 months later. Manager surveys focus on knowledge/awareness of IPV and company resources for IPV and number of referrals for IPV assistance. This extension is requested to cover the 12-month follow-up administration of this survey. Due to unexpected delays at the evaluation site and an inability to field the 6-month follow up survey with managers when originally scheduled, we will need to push the timeline for 12-month follow up back approximately 3 months.

We have also surveyed employees of those managers who completed the baseline survey using an anonymous Web-based survey at baseline. These

employees will also be surveyed 12 months later (during the extension period) to assess their self-evaluated productivity, absenteeism, and perceptions of manager behavior. We will compare the responses of managers (and their employees) who received the IPV training in the study period (*i.e.*, sometime between the baseline and 12 month surveys) with untrained managers. The study will provide CDC and employers information about the potential effectiveness and cost-effectiveness of workplace IPV intervention strategies.

There are no costs to respondents except their time to participate in the interview. The estimated total annualized burden hours are 1125.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondents    | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|----------------|-----------------------|------------------------------------|--|
| Manager .....  | 500                   | 3                                  | 30/60                                  |
| Employee ..... | 1500                  | 1                                  | 15/60                                  |

Dated: October 16, 2009.

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[FR Doc. E9-25531 Filed 10-22-09; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the

information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services (TCE-HIV)—NEW**

This data collection is to study the risk and protective factors related to substance use and HIV. The primary purpose of the Project is to conceptualize, plan, and implement a multi-site evaluation to investigate the process, outcome, and impact of substance abuse treatment and HIV/AIDS services provided by 49 SAMHSA grantees. The grantees' focus is on enhancing and expanding substance abuse treatment and/or outreach and pretreatment services in conjunction with HIV/AIDS services in African American, Hispanic/Latino, and other racial and ethnic minority communities. A multi-stage approach has been used to develop the appropriate theoretical framework, conceptual model, evaluation design and protocols, and

data collection instrumentation. Process and outcome measures have been developed to fully capture community and contextual conditions, the scope of the TCE-HIV Grantee program implementation and activities, and client outcomes. A mixed-method approach (survey, semi-structured interviews, focus groups) will be used, for example, to examine collaborative community linkages established between grantees and other service providers (*e.g.*, primary health care, medical services for PLWHA, substance abuse recovery support services), determine which program models and what type and amount of client exposure to services contribute to significant changes in substance abuse and HIV/AIDS risk behaviors of the targeted populations, and determine the impact of the TCE-HIV services on providers, clients, and communities.

The data collection for the project will be conducted bi-annually (*i.e.*, every other year during the 4 year period) and the client outcome data collection is ongoing throughout the project and will be collected at baseline, discharge and 6 months post baseline for all treated clients. The respondents are clinic-based social workers and counselors (*e.g.*, social workers, licensed alcohol and drug counselors, licensed clinical professional counselors, licensed