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) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Qualitative Evaluation of HIV Counseling, Testing, and Referral Services in Non-Health Care Settings: Eliciting Consumer Views—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Coordinating Center for Infectious Diseases (CCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Historically, HIV prevention efforts have targeted people at risk for HIV infection with the goal of keeping those who are HIV negative from becoming infected. However, the epidemic has changed with the introduction of highly active anti-retroviral therapy (HAART). People with HIV are now living longer, and with a steady incidence and increasing prevalence, an estimated 1,039,000 to 1,185,000 people are now living with HIV/AIDS in the United States. It is estimated that 25% of HIV-infected persons are not aware of their infection. Critical components in controlling the spread of HIV infection are early knowledge of HIV infection and access to treatment. Awareness of HIV infection has also been shown to reduce high risk sexual behaviors in some populations. Therefore, access to HIV counseling, testing, and referral (CTR) services can play a significant role in reducing HIV transmission.

This project involves formative research to elicit consumer opinions on HIV CTR in non-health care settings. The study entails conducting 21 focus groups with persons who are either HIV positive or at risk for HIV because of their drug injection or sexual behavior. The purpose of the focus groups is to explore: (1) Facilitators and barriers to use CTR services in non-health care settings; (2) ideal service components to decrease barriers to early diagnosis, decrease risk behaviors, link clients with follow-up care, and ensure client rights; (3) perceived risks and benefits of CTR; and (4) preferences for providing informed consent.

CDC will use study findings to inform the development of new recommendations for HIV CTR in non-health care settings. We expect a total of 630 individuals to be screened for eligibility. Of those who are screened, we expect that 252 individuals will join the study and participate in a focus group. There are no costs to the respondents other than their time. The total estimated annual burden hours are 714.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)
Prospective Participant	Screener	630	1	20/60
Adult Past Clients (HIV-negative)	Facilitator Guide—Adult Past Clients (HIV-negative).	60	1	2
Adult Past Clients (HIV-positive)	Facilitator Guide—Adult Past Clients (HIV-positive).	60	1	2
Adult Potential Clients	Facilitator Guide—Adult Potential Clients	60	1	2
Adolescents (HIV-positive)	Facilitator Guide—Adolescents (HIV-positive).	24	1	2
Adolescents (HIV-negative)	Facilitator Guide Adolescents (HIV-negative).	48	1	2

Dated: November 8, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22637 Filed 11–16–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0444]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

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 provisions of FDA's recordkeeping and records access requirements for food facilities.

DATES: Submit written or electronic comments on the collection of information by January 18, 2008.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *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 the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352 (OMB Control Number 0910–0560)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 414 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 through 1.363 (21 CFR 1.326 through 1.363) of FDA's regulations set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

FDA's regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and packaging, and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all of the required information and are retained for the required time period.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

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

This estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71630). With regard to records maintenance, FDA estimates that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, FDA estimates that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the agency estimates the number of new firms entering the affected businesses to be five percent (5%) of 379,493, or 18,975 firms. Thus, FDA estimates that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: November 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–2013]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

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.