

technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

“Evaluation of Pharmacy Syringe Access Linked to HIV Testing for Injection Drug Users in New York City (Pharm-HIV)”—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

HIV continues to be one of the leading causes of illness and death in the US, especially among black and Hispanic communities. For injection drug users (IDU), who are at high risk of acquiring HIV infection, HIV testing may not be readily accessible. In 2001, the New York State Legislature established an Expanded Syringe Access Demonstration Program (ESAP) in New York City which made syringes available through participating

pharmacies for injection drug users. ESAP thus helped to reduce the burden of HIV by increasing access to sterile syringe sources. The ESAP allows for regular contact between pharmacists and their injection-drug-using syringe customers, thus paving the way for pharmacies to act as access points to health and social services among IDU customers. The expansion of pharmacy services to include referrals for injection-drug-using syringe customers is based on the successes of ESAP, which provides many services beyond syringe exchange.

This project involves two kinds of studies: testing service models at pharmacies and, interviewing individuals regarding the availability of syringes through pharmacies. For testing service models CDC will collaborate with the New York Academy of Medicine (NYAM) to implement this project for a period of three years.

The NYAM will identify 12 ESAP pharmacies in East Harlem, New York

City; ten of which will test a model that refers injection-drug-using syringe customers for HIV testing to local HIV testing sites. Two ESAP pharmacies will evaluate the feasibility of offering and performing HIV counseling and testing in the pharmacy for injection-drug-using syringe customers.

Two types of respondents will provide the individual-level data; forty-eight adult (age ≥18 yrs) pharmacy staff members will be surveyed to learn about pharmacy staff attitudes and behaviors regarding HIV testing and referral. The other respondent group will be 442 adult (age ≥18 yrs) injection-drug-using syringe customers who will complete a brief quantitative interview after HIV referral or HIV testing is offered to them. HIV-seropositive injection-drug-using syringe customers identified during HIV testing will be immediately linked to social and medical services. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Types of data collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pharmacy telephone screening and enrollment form .....	24	1	10/60	4
Pharmacy staff surveys—baseline, every six months x 3, and at end of study. ....	48	5	20/60	80
Pharmacy staff brief surveys—monthly except when 6 monthly surveys are completed. ....	12	19	10/60	38
Pharmacy daily syringe sales log .....	12	600	5/60	600
Injection-drug-using syringe customer surveys .....	442	1	30/60	221
Total .....	.....	.....	.....	943

Dated: November 7, 2008.

**Maryam I. Daneshvar,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC),

announces the following meeting for the aforementioned subcommittee:

*Time and Date:* 9:30 a.m.–5 p.m., December 8, 2008.

*Place:* Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018. Telephone (859) 334-4611, Fax (859) 334-4619.

*Status:* Open to the public, but without a public comment period. To access by conference call dial the following information 1(866) 659-0537, Participant Pass Code 9933701.

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice

on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2009.

*Purpose:* The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood

that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

*Matters to be Discussed:* The agenda for the Subcommittee meeting includes: a discussion of cases under review from the 6th, 7th, and 8th sets of individual dose reconstructions; preparation of a letter report on the first 100 dose reconstruction cases reviewed; and, an update on site-specific dose reconstruction guidelines.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

*Contact Person for More Information:* Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta, GA 30333, Telephone (513) 533-6800, Toll Free 1(800) CDC-INFO, e-mail [ocas@cdc.gov](mailto:ocas@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 13, 2008.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letter of Intent .....	562	1	1	562

*Estimated Total Annual Burden Hours:* 562.

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 13, 2008.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E8-27358 Filed 11-18-08; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0526]

**Global Harmonization Task Force, Study Group 1; Proposed and Final Documents; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of proposed and final documents that have been prepared by Study Group 1 of the Global

*Title:* Letter of Intent for Indian Tribes, Tribal organizations or Tribal consortia to operate a title IV-E program under the Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub. L. 110-351).

*OMB No.:* New Collection.

*Description:* The Administration for Children and Families is requesting that Indian tribes, tribal organizations or tribal consortia that wish to apply for direct title IV-E funding pursuant to section 479B of the Social Security Act send a letter expressing their intent to facilitate budget and staff planning.

*Respondents:* Indian Tribes, Tribal organizations and Tribal consortia.

Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Group that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe FDA's current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

**DATES:** Submit written or electronic comments on these documents by February 17, 2009. After February 17, 2009, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

**ADDRESSES:** Submit written requests for single copies of these documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug