Background and Brief Description

This project seeks a one year extension of its OMB PRA clearance for data collection. Due to early project delays in obtaining clearances for data collection, the project was unable to start as planned and missed evaluating one program cycle, with a program cycle running for approximately one year. This extension is necessary in order to complete the project's original design of evaluating three program cycles of the SAIFE program as implemented in the State of North Carolina. An extension will allow completion of the evaluation of the third and final cycle of the program.

This project will use data from in-person interviews, paper and telephone surveys to assess the effectiveness of the Smoke Alarm Installation and Fire Safety Education (SAIFE) program and its efficacy in delivering fire safety information. The data will be collected from a convenience sample of adults 18 years of age or older who volunteer to participate in the SAIFE program. A total of 360 households will complete the evaluation each year of the data collection for a mass total of 1080 households over the next three years. Participants will be asked to complete a 15-minute survey at two points, once immediately before the intervention and then 6 months afterwards. The survey will assess outcome measures including, but not limited to, changes in knowledge, attitudes, beliefs, and behaviors regarding various aspects of fire safety and prevention; changes in reported residential fire-related injuries and deaths; increased or decreased presence of functioning smoke alarms; and the costs associated with the SAIFE intervention. The evaluation will measure these changes across time, between groups and within groups, among communities that will receive the SAIFE intervention.

CDC programs are currently funded in 16 States to provide for home installation of smoke alarms plus general fire safety education in households at high risk for fire and fire related injury and death. Programs of this type are intended to prevent fire related injury and mortality, but have not been studied scientifically to assess their impact on fire-related injury outcomes. The proposed study represents the first formal effort to evaluate the effectiveness and cost implications of the SAIFE program as implemented in North Carolina. The data collected in this study will have the potential to inform other smoke alarm installation programs, as well as indicate future priorities in prevention and preparedness for residential household fires. The only cost to the participant is the time involved to complete the surveys. The total estimated annualized burden hours are 251.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult male and female (age 18+ years) screened	425	1	5/60
Adult male and female (age 18+ years) Pre/Post Evaluation survey	360	2	15/60
Adult male and female (age 18+ years) household visit	36	1	1

Dated: August 26, 2009.

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

[30Day–09–09AF]

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

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, among injection drug users who are at high risk of acquiring HIV infection. HIV testing may not be readily accessible to this population in areas where they frequent. The New York State Legislature established an Expanded Syringe Access Demonstration Program (ESAP) in 2001 in New York City. ESAP makes sterile syringes available for injection drug users through participating pharmacies, in order to help reduce the burden of HIV. The regular contact between pharmacists and their injection-drug-using syringe customers through ESAP paves 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.

The New York Academy of Medicine (NYAM) has access to the ESAP list of pharmacies. NYAM will identify 12 ESAP pharmacies in East Harlem, New York City that are situated within predefined target neighborhoods where there are high levels of injection drug use. NYAM study staff will screen the ESAP pharmacies for eligibility by calling down a randomly-ordered list of ESAP-registered pharmacies and enrolling pharmacies willing to participate in this study. NYAM anticipates that they will have to contact 24 ESAP-registered pharmacies in the first year of the project (one pharmacy staff member at each pharmacy) in order to identify the 12 that will participate in the study. Recruitment of pharmacies will occur only during the first year.

At the 12 ESAP-registered pharmacies that join the study, over a three year period, 442 adult (age ≥18 yrs) injection-drug-using syringe customers will

complete a brief quantitative interview after HIV referral or HIV testing is offered to them. HIV-seropositive injection-drug-using syringe customers who are identified during HIV testing will be immediately linked to social and medical services. Ten of the 12 ESAP Pharmacies will provide referrals to local HIV testing sites for their injection-drug-using syringe customers. At these ten pharmacies, 40 adult pharmacy staff will be surveyed on pharmacy staff attitudes and behaviors regarding HIV testing and referral.

The remaining two ESAP pharmacies will pilot test the feasibility of offering and performing HIV counseling and testing in the pharmacy for injection-drug-using syringe customers. At these two pharmacies, 8 adult (age ≥18 yrs) pharmacy staff members will be surveyed on pharmacy staff attitudes and behaviors regarding HIV testing and referral. At the 12 pharmacies, 12 pharmacy staff members (one from each pharmacy) will be surveyed monthly to track study progress and obstacles to completing the study. Twelve pharmacy staff members (one from each pharmacy) will complete a daily syringe sales and referral log.

There is no cost to the injection drug using customers who provide information to this study other than their time. The total estimated annual burden hours are 496 hours.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondent	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
Pharmacist	Pharmacy telephone screening and enrollment form.	8	1	10/60
Pharmacist and Pharmacy Technician	Pharmacy staff baseline survey	48	1	20/60
Pharmacist and Pharmacy Technician	Pharmacy staff six monthly survey	48	2	20/60
Pharmacist and Pharmacy Technician	Pharmacy staff exit survey	48	1	20/60
Pharmacist	Pharmacy staff monthly survey	12	10	10/60
Pharmacy Technician	Syringe sales and referral log	12	300	5/60
Syringe-customer study participant	Pharmlink Participant Baseline Survey	221	1	30/60

Dated: August 26, 2009.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0131]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Marketing Act of 1987

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 October 1, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792, Elizabeth.Berbakos@fda.hhs.gov.

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.

Prescription Drug Marketing Act of 1987; 21 CFR Part 203 (OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501–3520) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Public Law 100–293). PDMA was intended to ensure that drug products purchased by consumers are safe and effective, and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against U.S. manufacturers and had provided the cover for the importation of foreign counterfeit drugs.

Congress also determined that the system of providing drug samples to physicians through manufacturers' representatives had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

The bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail also helped to fuel the diversion market and was an unfair form of competition to wholesalers and retailers who had to pay otherwise prevailing market prices.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements: