Dated: May 26, 2009.

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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–09–05CS]

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

Proposed Project

Nurse Delivered Risk Reduction Intervention for HIV-Positive Women—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

During the past two decades, HIV surveillance data indicates an increase in HIV/AIDS cases among women in the non-urban Southeastern United States. In 2006, the majority of HIV/AIDS cases (80%) among women were attributed to high-risk heterosexual contact with an infected partner. Black women in particular have been disproportionately impacted by HIV/AIDS. Factors shown to be associated with HIV in the South include poverty, lack of access to medical care, poor education, lack of awareness of the disease, and exposure to other sexually transmitted diseases. Presently, there is an urgent need for enhanced HIV transmission prevention interventions for HIV positive women in the southeastern United States.

The purpose of this project is to adapt and test the efficacy of an HIV transmission prevention intervention for reducing sexual risk among 330 HIV-positive women in North Carolina and to identify factors associated with risk among women. The study will be conducted in two parts (intervention trial and individual in-depth interviews). The intervention trial will evaluate a brief, nurse delivered, single session intervention. The trial will use a randomized wait-list comparison design with a three-month follow-up assessment. To determine eligibility for participation in the study, a brief, in-person, screening will be used. Eligible participants will complete baseline and follow-up behavioral assessments. The assessments contain questions about participants' background, health and health care, sexual activity, substance use, and other psychosocial issues. The in-depth interviews will be conducted with a subgroup of 25–30 women. The purpose of the in-depth interviews is to assess experiences with the intervention, elicit recommendations for developing risk reduction intervention strategies, and to better understand the factors that place women at risk for HIV. Study participants will be recruited from health departments and clinics providing healthcare to HIV-positive women and AIDS Service Organizations. There is no cost to the participants other than their time. The total estimated annual burden hours are 635.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
Potential Participants	Screener Contact Form	550	1	10/60
Intervention Participants—and Comparison Group)	Locator Form	330	1	3/60
Intervention Participants—and Comparison Group	Assessment Baseline	330	1	45/60
Intervention Participants—and Comparison Group	Assessment Follow-up	330	1	45/60
Subset of Intervention Group	In-depth Interview	30	1	1

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0464] (formerly Docket No. 2005N–0403)

Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' This guidance document is designed to assist industry (e.g., manufacturers, repackers, and relabelers) with the electronic submission of drug establishment registration and drug listing information. Specifically, the document provides guidance to industry on the types of information to include for purposes of drug establishment registration and drug listing and on how to prepare and submit the information in an electronic format that FDA can process, review, and archive.

DATES: Submit written or electronic comments on agency guidances at any time. As of June 1, 2009, FDA will only accept electronic submissions of drug establishment registration and drug