Dated: May 26, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–12630 Filed 5–29–09; 8:45 am]

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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

Dated: May 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

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

listing information, unless a waiver is granted.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling the Office of Critical Path Programs at 301–827–1512. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lonnie Smith, Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0011.

SUPPLEMENTARY INFORMATION:

I. Background

Requirements for drug establishment registration and drug listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) and 21 CFR part 207. Fundamental to FDA's mission to protect the public health is the collection of this information, which is used for important activities such as postmarket surveillance for serious adverse drug reactions, inspection of drug manufacturing and processing facilities, and monitoring of drug products imported into the United States. Comprehensive, accurate, and up-to-date information is critical to conducting these activities with efficiency and effectiveness.

Changes in the act, resulting from the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), require that drug establishment registration and drug listing information be submitted electronically, unless a waiver is granted. Before FDAAA was enacted, section 510(p) of the act expressly provided that drug establishment registration information must be submitted electronically, based on a finding that electronic receipt was feasible, and section 510(j) of the act stipulated that drug listing information must be submitted in the form and manner prescribed by FDA. Section 224 of FDAAA, which amends section 510(p) of the act, now expressly requires drug listing to be submitted by electronic means in addition to requiring electronic drug establishment registration.

Drug establishment registration and drug listing information have, until now, been submitted using a paper-based format, i.e., Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors). Moving from a paper-based format to an electronic system will improve the timeliness and accuracy of the submissions.

This guidance is designed to assist manufacturers, repackers, and relabelers with electronic submissions of drug establishment registrations and drug listing information. The guidance and accompanying technical documents explain (among other things):

- The statutory requirement to submit electronically drug establishment registration and drug listing information;
- How to create a Structured Product Labeling (SPL) file for submitting drug establishment registration and drug listing information to FDA through the Electronic Submissions Gateway (ESG) using defined code sets and codes, i.e., a language recognized by the computer system; and
- That FDA intends to no longer accept drug establishment registration and drug listing information in paper format, unless a waiver is granted. FDA encourages manufacturers, repackers, and relabelers to establish a gateway account as soon as possible so that they will be prepared to electronically submit drug establishment registration and drug listing information by June 1, 2009.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on providing regulatory submissions in electronic format for drug establishment registration and drug listing information. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in this guidance was approved under OMB control number 0910–0045.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/cvm/guidance/guidance.html*, and *http://www.regulations.gov*.

Dated: May 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held August 4, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727