report forms enable CDC to collect demographic, clinical, and laboratory characteristics of cases of these diseases. This information is used to direct epidemiologic investigations, to identify and monitor trends in reemerging infectious diseases or emerging modes of transmission, to search for possible causes or sources of the diseases, and to develop guidelines for the prevention of treatment.

CDC proposes to separate the two HIV/AIDS case reports from the current clearance in order to have the case reports sent to the appropriate CDC organizational entity. Under the current clearance these forms are managed by the staff within the National Centers for Infectious Diseases (NCID). Separating the packages into two clearances will be more efficient for CDC. These forms are used to report all HIV/AIDS cases for children and adults in all 50 states, Guam, the Pacific Islands, Puerto Rico, and the Virgin Islands. The information collected and the methodology used will remain the same. The data will continue to be used for the purposes described in the previous paragraph. The total annualized burden is 4,373 hours. The total cost to respondents is estimated at $65,595.

Respondents	Number of respondents	Number of responses per respondent	Average burden per respondent (in hrs.)
HIV/AIDS Adult Case Report	55	473	10/60
HIV/AIDS Pediatric Case Report	55	4	10/60

Dated: January 2, 2001.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–14–01]

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) 639–7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Geo-Analysis of HIV Prevention Services Provided by CDC to Directly and Indirectly Funded Community-Based Organizations (CBOs). NEW—The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP), Division of HIV/AIDS Prevention (DHAP) proposes an evaluation project which will build on the knowledge gained from the previous studies to provide a multi-level, geo-referenced review of CDC-funded, community-based organization (CBO)-provided HIV prevention services. The purposes of this project are: (1) To contribute to the construction of a national database of HIV prevention activities by developing a geo-coded database that identifies, locates and maps all CBOs directly and indirectly funded by CDC in the US and its territories, and (2) to evaluate the comprehensiveness of HIV prevention services in geographic areas across the United States of America and territories through the use of Geographic Information Systems (GIS) technology as the primary analytical tool.

This project is being tasked under the Enhanced Program Assessments with Laboratory Capability Task Order Contract (200–96–0511) because of its program evaluation component. By using GIS to identify gaps in service provision within a given geographic area, program changes can be recommended to those health departments and CBOs participating in the project. These recommended changes may include adjusting services provided or target populations in an effort to close identified gaps.

Collaboration between government agencies and CBOs with access to a particular group at risk has been a traditional approach in public health in the United States. CDC promotes the collaboration and coordination of HIV prevention efforts between CBOs and of CBOs with State health departments, affiliates of National and Regional Minority Organizations(NRMOs), HIV prevention service agencies, and other public agencies including substance abuse programs, educational institutions and the criminal justice system. CDC promotes collaboration as a strategy for (1) improving access to and for at risk populations and communities, (2) improving the direct delivery of services, (3) improving referral of clients to services, and (4) creating comprehensive HIV services in designated geographical jurisdictions.

The use of GIS will enhance the accomplishment of these three goals by providing information to funders and other shareholders to enhance CBOs in their efforts to provide interventions and client referrals and services that are accessible to the populations in need of them. This data will assist the CDC to determine the effectiveness of federal funding, whether the funding is affecting the designated high risk or infected groups such as disproportionately affected minorities where they live, or whether or not there are available programs to link with for more comprehensive services.

The project will use appropriate technology to minimize respondent burden. A self-report mailed questionnaire, three pages in length, will be mailed. Attached, will be two maps of the geographical area (city and surrounding metropolitan area) where each CBO is located. The use of maps eliminates the need to locate maps to respond to questions concerning location and distance. This project will not be requesting information of a sensitive nature. The project deals with the types of interventions offered to high risk or HIV positive individuals, location and access.

The CDC anticipates one person per CBO (total # of approximately 2000) to complete the data collection form once during the 2000 for approximately 30 minutes. Therefore, the total response burden is estimated at 1000 hours.

Respondents	Number of respondents	Number of responses	Average hour burden per response
Directly Funded CBOs	184	1	30/60
Indirectly Funded CBOs	1816	1	30/60

Dated: January 2, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–475 Filed 1–8–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1669]

Electronic Filing of Drug Registration and Listing Information: Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking volunteers to participate in a pilot project involving the electronic filing of drug registration and listing information, as described in FDA's regulations. Manufacturers, repackers, and relabelers who engage in the manufacture, preparation, propagation, or processing of human or veterinary drugs and human biological products are required under current regulations to submit a listing of every product in commercial distribution. This information is currently submitted in paper format. FDA is developing an electronic system for submitting the required information, and is seeking volunteers to test the pilot system.

DATES: Submit written requests to participate in the pilot project by February 8, 2001. Comments on this pilot project can be submitted at any time.

ADDRESSES: Submit written requests to participate and comments regarding this pilot project to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–9), 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779, e-mail: hunterj@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under current FDA's regulations (part 207 (21 CFR part 207)), manufacturers, repackers, and relabelers who engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and human biological products must register annually with FDA by submitting Form FDA 2656 (Registration of Drug Establishment). In addition, registrants must update their product listing information by using Form FDA 2657 and/or Form FDA 2658 every June and December, or at the discretion of the establishment, when any change occurs. This entire process is currently done manually (i.e., with a paper process). This process is very labor intensive and time consuming. FDA is trying to streamline the process by developing an electronic system in which registrants could automatically register and list, as well as provide updates.

The purpose of the pilot project is twofold. First, the pilot project will test FDA's systems for receiving electronic filings under part 207. Second, the pilot project will provide volunteers with experience in using the prototype system that will enable them to provide technical feedback to FDA about the system.

II. Pilot Project Description

The pilot project is part of FDA's efforts to implement electronic filing. Eventually, FDA staff expects to recommend that FDA require electronic filings under part 207. Participants in this pilot project will have the opportunity not only to assist FDA in making its determination on electronic filing, but also to familiarize themselves with the process at an early stage of development.

A. Initial Approach

Initially, a limited group of voluntary participants will take part in testing the electronic filing prototype. This group will be incrementally expanded during the pilot project to ensure that as many volunteers as possible get the opportunity to participate and that all functional components of the system are adequately tested. The initial group of participants will include manufacturers, repackers, relabelers, and private label distributors of human prescription and over the counter drug and biological products and manufacturers of veterinary drug products that currently have more than 25 products listed with the agency. During the pilot project, information submitted will be made available to the public by the agency via the Internet at http://www.fda.gov/cder. Participants in the pilot project will be asked to test specific aspects of the electronic filing system and to provide technical feedback.

B. Scope

Existing registration and listing requirements will not be waived, suspended, or modified for purposes of this pilot project. Thus, participants must continue to submit paper documents in accordance with FDA's existing filing requirements (part 207). The paper copy will serve as the official copy under existing regulations during the pilot project.

The pilot project will test a prototype for electronic filing over the Internet of information to fulfill the requirements of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

Written requests to participate in the pilot project should be submitted to the Dockets Management Branch (address above) and identified with the docket number found in brackets in the heading of this document. Include the participants name, company name, company address, and telephone number. In addition, include in your written request to participate the number of products you currently have listed with the agency, the number of establishments you currently have registered with the agency, the type of products you process (i.e., human, biologic, or veterinary), the process(es) you perform (i.e., manufacture, repackage, relabel, distribute), and the kind of products you process (i.e., prescription, over the counter, active pharmaceutical ingredients (bulk), or, homeopathic).

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this pilot project. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will