

disaggregate Asian/Pacific Islander into two categories: Asian and Native Hawaiian/Other Pacific Islander.

No other federal agency collects this type of national HIV/AIDS data. In addition to providing technical assistance for use of the case report

forms, CDC also provides reporting areas with technical support for the HARS software. There is no cost to respondents.

Form	Number of respondents	Number of responses/respondent	Average burden/response/ (in hours)	Total burden (in hours)
Adult Case Report: AIDS	55	782	10/60	7,168
Adult Case Report: HIV	35	1007	10/60	5,874
Peds Case Report: AIDS	55	3	10/60	28
Peds Case Report: HIV	35	16	10/60	93
Total	13,163

Dated: July 19, 2002.

Nancy E. Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-39-02]

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) 498-1210. 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: Report of Verified Case of Tuberculosis (RVCT) (CDC 72.9A, 72.9B, 72.9C) OMB No. 0920-0026—Revision—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention

(NCHSTP), Division of Tuberculosis Elimination (DTBE), proposes to continue data collection for the Report of Verified Case of Tuberculosis (RVCT) (CDC 72.9A, 72.9B, 72.9C), previously approved under OMB No. 0920-0026 in 1992, 1995, 1998, and 2001. This request is for a 3-year revision of OMB clearance approval beginning January 1, 2003 (current OMB No. 0920-0026 expiration date is December 31, 2002). CDC is requesting OMB clearance for revision of the RVCT which will change the race and ethnicity variables on the RVCT form to comply with the OMB “Standards for Maintaining, Collecting, and Processing Federal Data on Race and Ethnicity”.

To accomplish the CDC goal of eliminating tuberculosis (TB) in the United States, CDC maintains the national TB surveillance system. The system, initiated in 1953, has been modified several times to better monitor and respond to changes in TB morbidity. The most recent modification was implemented in 1993 when the RVCT was expanded in response to the TB epidemic of the late 1980s and early 1990s and incorporated into a CDC software for electronic reporting of TB case reports to CDC. The expanded system improved the ability of CDC to monitor important aspects of TB epidemiology in the United States, including drug resistance, TB risk factors, including HIV coinfection, and treatment. The timely system also enabled CDC to monitor the recovery of the nation from the resurgence and identify that current TB epidemiology supports the renewed national goal of elimination. To measure progress in

achieving this goal, as well as continue to monitor TB trends and potential TB outbreaks, identify high risk populations for TB, and gauge program performance, CDC proposes to extend use of the RVCT.

Data are collected by 60 Reporting Areas (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean) using the RVCT. An RVCT is completed for each reported TB case and contains demographic, clinical, and laboratory information. A comprehensive software package, the Tuberculosis Information Management System (TIMS) is used for RVCT data entry and electronic transmission of TB case reports to CDC. TIMS provides reports, query functions, and export functions to assist in analysis of the data. CDC publishes an annual report summarizing national TB statistics and also periodically conducts special analyses for publication in peer-reviewed scientific journals to further describe and interpret national TB data. These data assist public health officials and policy makers in program planning, evaluation, and resource allocation. Reporting Areas also review and analyze their RVCT data to monitor local TB trends, evaluate program success, and assist in focusing resources to eliminate TB.

No other federal agency collects this type of national TB data. In addition to providing technical assistance for use of the RVCT, CDC also provides Reporting Areas with technical support for the TIMS software. There annualized burden for this data collection is 8,338 hours.

Respondents	Number of respondents	Responses per respondent	Average burden per response (in hours)
State/Local/Tribal Governments	60	278	30/60

Dated: July 17, 2002.

Nancy E. Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of Industry Interests on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting representatives of industry interests to serve on the Blood Products Advisory Committee, in the Center for Biologics Evaluation and Research (CBER). Nominations will be accepted for vacancies that will or may occur through September 30, 2003.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the biologics and/or drug industry.

DATES: Nominations should be received by July 30, 2002.

ADDRESSES: All nominations and curricula vitae should be sent to Linda A. Smallwood (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Linda A. Smallwood, Office of Blood Research and Review, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6128.

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act (FDAMA) of 1997 (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the biologics and/or drug manufacturing industries. This announcement is soliciting nominations for the committee listed below:

Blood Products Advisory Committee:

One vacancy occurring in September 30, 2002; clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, statistics, biological and physical sciences, and other related scientific fields.

I. Function

Reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood and products intended for use in the diagnosis, prevention, or treatment of human diseases.

II. Nomination Procedures

Any organization in the blood, medical device and/or biologics manufacturing industry wishing to participate in the selection of an appropriate nonvoting industry representative for the Blood Products Advisory Committee should notify the contact person of their interest in nominating one or more qualified persons. Persons who nominate themselves as representatives of industry interests for a certain advisory committee may not participate in the overall selection process.

Nominees should be familiar with firms that manufacture products regulated by the agency including biologics and/or drug manufacturers. Nomination packages should include the name of the committee and the nominee's willingness to serve on the committee. To ensure that the nomination process continues within the set timelines, submitters are strongly encouraged to include a complete curriculum vitae for each nominee with the letter of nomination. The term of office is up to 4 years.

III. Selection Procedure

A letter will be sent to each nominating organization that submitted a nomination package to FDA for a particular advisory committee. The letter will provide the complete list of all nominees. It is the responsibility of each nominating organization to consult with one another to select a single member to represent the industry interests for the advisory committee. This must be completed within 60 calendar days. If no individual is selected, the Commissioner of Food and Drugs will select a nonvoting member to represent the industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: July 18, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; 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: Antiviral Drugs Advisory Committee.

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 on August 6 and 7, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 6, 2002, the committee will discuss new drug application (NDA) 21-449, adefovir dipivoxil tablets, Gilead Sciences, Inc., proposed for treatment of chronic hepatitis B infection (HBV). On August 7, 2002, the committee will discuss clinical trial design issues in the development of products for the treatment of chronic hepatitis B infection.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 30, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted