

*Proposed Project:* National Surveillance of Dialysis-Associated Diseases (0920-0033)—Extension—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). The Division of Healthcare Quality Promotion (DHQP; formerly Hospital Infections Program), is proposing an extension of a yearly survey of dialysis practices and dialysis-associated diseases at U.S. outpatient hemodialysis centers. The rehabilitation of individuals in the United States who suffer from chronic renal failure has been identified as an important national priority; since 1973, chronic hemodialysis patients have been provided financial support by the

Federal Government. DHQP and the Division of Viral Hepatitis have responsibility for formulating strategies for the control of hepatitis, bacteremia, and other hemodialysis-associated diseases.

In order to devise such control measures, it is necessary to determine the extent to which the incidence of these dialysis-associated diseases changes over time. This request is to continue surveillance activities among chronic hemodialysis centers nationwide. In addition, once control measures are recommended it is essential that such measures be monitored to determine their effectiveness. The survey is conducted

once a year by a mailing to all chronic hemodialysis centers licensed by the Health Care Financing Administration. The types of dialysis practices surveyed include the use of hepatitis B vaccine in patients and staff members, the types of vascular access and dialyzers used, whether certain dialysis items are disinfected for reuse, and whether the dialysis center has any policy for insuring judicious use of antimicrobial agents. Among dialysis-associated diseases, the survey includes hepatitis B virus infection, antibody to hepatitis C virus, antibody to human immunodeficiency virus, and vancomycin-resistant enterococci. There are no costs to respondents.

| Respondents                        | Number of respondents | Number of responses/respondent | Avg. burden/response (in hours) | Total burden (in hours) |
|------------------------------------|-----------------------|--------------------------------|---------------------------------|-------------------------|
| Chronic Hemodialysis Centers ..... | 3,800                 | 1                              | 1                               | 3,800                   |
| Total .....                        | .....                 | .....                          | .....                           | 3,800                   |

Dated: April 1, 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

[60Day-02-38]

#### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498-1210.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)

ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Project:* Report of Verified Case of Tuberculosis (RVCT) (CDC 72.9A, 72.9B, 72.9C) OMB No. 0920-0026—Extension—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 is no cost to respondents.

| Respondents                                     | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total response burden (in hours) |
|-------------------------------------------------|-----------------------|------------------------------------|----------------------------------------|----------------------------------|
| Local/State/Territorial Health Department ..... | 60                    | 278                                | 30/60                                  | 8340                             |
| Total .....                                     | .....                 | .....                              | .....                                  | 8340                             |

Dated: April 2, 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

#### Drug Information Association and Food and Drug Administration on the Fourth Project Management Workshop: Effective Agency/Industry Interactions to Expedite Drug Development; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) in cosponsorship with the Drug Information Association (DIA) is announcing a public workshop entitled "The Fourth Project Management Workshop: Effective Agency/Industry Interactions to Expedite Drug Development." The workshop will focus on facilitating drug development and drug review processes.

**Date and Time:** The workshop will be held on April 30, 2002, from 8:30 a.m. to 5 p.m., May 1, 2002, from 8:30 a.m. to 5 p.m., and May 2, 2002, from 8:30 a.m. to 12:30 p.m.

**Location:** The workshop will be at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD.

**Contacts:** For information about this notice: Michael D. Anderson, Center for Biologics Evaluation and Research (CBER) (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6210,

FAX 301-594-1944, e-mail:

Andersonm@cber.fda.gov.

**For information about the workshop:** David Roeder, Center for Drug Evaluation and Research (CDER) (HFD-104), Food and Drug Administration, 9201 Corporate Blvd. Rockville, MD 20850, 301-827-2488, FAX 301-827-2520, e-mail: Roederd@cder.fda.gov, or Gail Sherman, Center for Biologics Evaluation and Research (HFM-42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000, FAX 301-827-3079, e-mail: Sherman@cber.fda.gov, or Camela Pastorius, Drug Information Association (DIA), 501 Office Center Dr., suite 450, Fort Washington, PA 19034, 215-591-3303, FAX 215-641-1229, e-mail: Camela.Pastorius@diahome.org. If you need special accommodations due to a disability, please contact Camela Pastorius (address above) by April 23, 2002.

**Registration:** Mail or fax your registration information and registration fee to DIA, P.O. Box 7777-W8405, Philadelphia, PA 19175. You may obtain registration forms from DIA (see contact information) or from FDA at <http://www.fda.gov/cber/meetings.htm>. Additional information regarding registration fees and online registration can be found at <http://www.diahome.org/docs/Events/Events-search-detail.cfm?EventID=0201>.

**SUPPLEMENTARY INFORMATION:** FDA (CBER and CDER) and DIA are cosponsoring a workshop as part of a continuing effort to develop higher levels of teamwork, communication, and procedural knowledge to facilitate drug development and review in the United States. The workshop's target audience is FDA regulatory project managers and pharmaceutical industry project management and regulatory teams who have mid-level experience

and are involved in daily agency-industry interactions.

The workshop will present three major themes:

- **Planning and Teamwork**—attendees will participate in activities designed to highlight the value of teamwork, and to exchange ideas about team organization and management;

- **Understanding the Process of Regulatory Project Management**—the workshop will explore parallel objectives and activities within industry and FDA and identify opportunities for effective interaction. Attendees will also share ideas for optimizing working relationships between project management and regulatory professionals and between industry representatives and FDA regulatory project managers;

- **Key Factors for Success**—the workshop will present a set of experience-based factors for successful FDA/industry interaction.

Dated: April 4, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of May 2002.