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[FR Doc. 97–19892 Filed 7–28–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–17–97]

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 Office on (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

1. National Surveillance System for Hospital Health Care workers (NASH)—New—CDC has developed a surveillance system that focuses on surveillance of exposures and infections among hospital-based health care workers (HCWs). This system, modeled after the National Nosocomial Infections Surveillance (NNIS) system for patient infections, includes standardized methodology for various occupational health issues (OMB 0920–0012). The Hospital Infections Program, National Center for Infectious Diseases (NCID) has developed this system in collaboration with the Hepatitis Branch, Division of Viral and Rickettsial Diseases, NCID; the Division of Tuberculosis (TB) Elimination, National Center for HIV, STD, and TB Prevention; the National Immunization Program (NIP), and the National Institute for Occupational Safety and Health (NIOSH).

The NASH system consists of modules for collection of data about various occupational issues. Baseline information about each HCW such as demographics, immune-status for vaccine-preventable diseases, and TB status is collected when the HCW is enrolled in the system. Results of routine tuberculin skin test (TST) are collected and entered in the system every time a TST is placed and read. In the event that an HCW is exposed to blood/bloodborne pathogen, to a vaccine-preventable disease, or to a TB infectious patient/HCW, epidemiologic data will be collected about the exposure. For HCWs exposed to a bloodborne pathogen (i.e., HIV, HCV, or HBC), follow-up data will be collected during the follow-up visits. Once a year, the hospitals will perform a survey to assess the level of under reporting of needlesticks (HCW Survey) and will complete a hospital survey to provide denominator data. Data will be sent entered into the software and diskettes will be sent to CDC. No identifiers of the HCW will be sent to CDC. This system is protected by the Assurance of Confidentiality (308d).

Data collected in this surveillance system will assist hospitals, HCWs, HCW organizations, and public health agencies. This system will allow CDC to monitor national trends, to identify newly emerging hazards for HCWs, to assess the risk of occupational infection, and to evaluate preventive measures, including engineering controls, work practices, protective equipment, and postexposure prophylaxis to prevent occupationally acquired infections. Hospitals who volunteer to participate in this system will benefit by receiving technical support and standardized methodologies, including software, for conducting surveillance activities on occupational health.

This system has been developed and piloted in large teaching hospitals. Prior to implementation in a nationwide network of hospitals, an expansion of this pilot project to include more medium/small size hospitals is essential for further refinement of protocols and software. The first pilot project ran from October 1994 to September 1996 (RFP–200–94–0834(P)) and included four hospitals; the second pilot started in October 1996 (RFP–200–96–0524(P)) and includes five hospitals. Fifteen hospitals are expected to participate in this proposed project, including the five currently participating. Once the expanded pilot project is completed, the system will be made available to all short-term care hospitals in the United States who wish to voluntarily participate in this project. The total annual burden hours are 14,554.

Respondents	Number of respondents	Number of responses/ respondents	Average burden/response (in hours)
Baseline Information Form	15	1,500	0.3333
TST—Result Form	15	1,500	0.1666
TST—Evaluation Form	15	13	0.1666
Exposure to Blood Form	15	100	0.4166
Exposure to Blood Follow-up Form	15	50	0.25
Exposure to vaccine-prv. dis—Summary Form	15	8	0.3333
Exposure to vaccine-prv. dis—HCW Form	15	16	0.3333
Exposure to TB Form	15	3	0.50
Exposure to Non-Infectious Injury Form	15	133	0.3333
Exposures to Blood During Surgery Form	15	80	0.1666
Exposures to Blood During OB Deliveries Form	15	80	0.1666
HCW Survey	15	500	0.1666

* The same 15 hospitals will be completing the 12 separate forms listed above. The number of respondents includes x number of employees times each of 15 hospitals.

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[FR Doc. 97–19893 Filed 7–28–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0453]

Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation.'' The purpose of the guidance document is to assist facilities involved in recovery, infectious disease testing, screening, processing, storing, or distributing human tissue intended for transplantation. The guidance document provides information on procedures and practices for donor screening and testing. FDA prepared the guidance document after receiving public input. The topics included in the guidance document were contained in a draft document ''Screening and Testing of Donors of Human Tissue Intended for Transplantation'' made available for discussion at a public workshop on human tissue held on June 20 and 21, 1995.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the ''Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844.

Persons with access to the Internet may obtain the document using File Transfer Protocol (FTP), the World Wide Web (WWW), or bounce–back e–mail. For FTP access, connect to CBER at ''ftp://ftp.fda.gov/cber/''. For WWW access, connect to CBER at ''http://www.fda.gov/cber/publications.htm''. To receive the document by bounce–back e–mail, send a message to ''tissue2@a1.cber.fda.gov''.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except individuals may submit one copy. Requests and comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA published an interim rule on human tissue intended for transplantation to reduce the risk of transmission of human immunodeficiency virus (HIV) and hepatitis through human tissue intended for transplantation. The interim rule was issued under the authority of sections 215, 311, 361, and 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271) because of an immediate need to protect the public health from the transmission of communicable diseases through the transplantation of human tissue. The interim rule established requirements for the testing of donors of human tissue for HIV Type 1 virus, HIV Type 2 virus, hepatitis B virus, and hepatitis C virus. The interim rule also required that donors be screened for medical history, including behaviors that carry an increased risk of exposure to these viruses (behavioral and high risk information) and for signs and symptoms of infection with these viruses.

In the **Federal Register** of June 20, 1995 (60 FR 32128), FDA announced the availability for public comment of a draft document entitled ''Screening and Testing of Donors of Human Tissue Intended for Transplantation.'' The availability of the draft document coincided with the workshop on Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives which was held on June 20 and 21, 1995. Comments received on this draft document and the issues discussed at the workshop were considered in the development of the guidance document being announced in this notice.

This guidance document provides general information on the following procedures: (1) Determination of donor suitability, (2) evaluation of screening test performance, (3) application of a plasma dilution algorithm to determine the acceptability of the blood specimen used for testing, (4) screening for behavioral and high risk information, and (5) evaluation of clinical and physical evidence of infection with HIV or hepatitis.

As technical standards change over time due to an increased understanding of infectious diseases and improved technology for testing, FDA may issue future guidance to help ensure that the regulatory process reflects the current level of knowledge. The recommendations in this guidance document should be considered in addition to voluntary standards developed and used by human tissue organizations.

This document is not being issued under the authority of 21 CFR 10.90(b) because FDA is in the process of revising this section. As with other guidance documents, FDA does not intend this document to be all–inclusive. This document does not bind the agency and does not create or confer any rights, privileges, or benefits for or on any person. Tissue facilities may follow the guidance document or may choose to use alternative procedures not provided in the guidance document. If a tissue facility chooses to use alternative procedures, the facility may wish to discuss the matter further with the agency to prevent expenditure of resources on activities that may be unacceptable to FDA.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments 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. Continued comment by the human tissue industry is encouraged, and comments will be continuously accepted by the Dockets Management Branch.

FDA periodically will review written comments on the guidance document to