

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 at (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 Seleda Perryman, 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: "Reactions to Race" Module for the General Social Survey (GSS)—New—National Center for*

Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

The purpose of this data collection is to understand some of the contextual, perceptual, and experiential factors associated with reactions to "race" that may contribute to racial disparities in health outcomes. CDC will fund "Reactions to Race" data collection on the 2004 General Social Survey (GSS). The Measures of Racism Working Group at CDC developed a 10-question module in the GSS.

The GSS is a biennial national population-based in-person survey conducted by the National Opinion Research Center (NORC) at the University of Chicago. GSS first data collection was in 1972. The basic purpose of the GSS is to continue "to gather data on contemporary American society in order to monitor and explain trends and constants in attitudes, behaviors, and attributes; to examine the structure and functioning of society in general as well as the role played by relevant subgroups; to compare the United States to other societies in order to place American society in comparative perspective and develop cross-national models of human society; and to make high-quality data easily accessible to scholars, students, policy

makers, and others, with minimal cost and waiting" (*see http://www.norc.uchicago.edu/projects/gensoc1.asp*).

CDC is contracting with NORC through an existing agreement to administer the "Reactions to Race" module to the full GSS sample, consisting of 3,000 non-institutionalized U.S. adults, starting in June 2004. The questionnaire will be administered in-person by trained interviewers who have been "race"-matched with the predominant "race" of residents in each sampled area.

The distributions of responses to the questions on the "Reactions to Race" module will be examined across all respondents as well as compared by "race". In addition, we will look at the relationship between the responses from the "Reactions to Race" module and responses to other health, attitude, and behavior questions (including a detailed assessment of experiences at work) on the 2004 GSS. These other data will provide a rich resource to help us contextualize responses to the module.

Ultimately, the results from this data collection will be useful as we examine the causes of and design interventions to eliminate racial and ethnic health disparities. There are no costs to respondents.

Respondent	Number of respondents	Number of responses/respondent	Avg. burden/response (in hours)	Total burden (in hours)
U.S. Adults .....	3,000	1	5/60	250
Total .....	.....	.....	.....	250

Dated: September 25, 2003.

**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**

**Advisory Committee on Childhood Lead Poisoning Prevention**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

*Name:* Advisory Committee on Childhood Lead Poisoning Prevention.

*Times and Dates:*  
8:30 a.m.–5 p.m., October 14, 2003  
8:30 a.m.–12:30 p.m., October 15, 2003.

*Place:* Embassy Suites—Atlanta at Centennial Olympic Park, 267 Marietta Street, Atlanta, Georgia 30313. Telephone 404/223 2300.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

*Purpose:* The Committee shall provide advice and guidance to the Secretary; the Assistant Secretary for Health; and the Director, CDC, regarding new scientific knowledge and technological developments and their practical implications for childhood lead poisoning prevention efforts. The Committee shall also review and report regularly on childhood lead poisoning prevention practices and recommend improvements in national childhood lead poisoning prevention efforts.

*Matters to be Discussed:* Agenda items include: Update on Primary Prevention issues, Review of Evidence for Effects at Blood Lead Levels <10 µg/dL, Building

Blocks Project, the National Academy of Sciences Study, Lead Exposure at Superfund Sites, and the Update on International Lead issues.

Agenda items are subject to change as priorities dictate.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time of each presenter.

*For Further Information Contact:* Crystal M. Gresham, Program Analyst, Lead Poisoning Prevention Branch, Division of Emergency and Environmental Health Services, NCEH, CDC, 4770 Buford Hwy, NE, M/S F-30, Atlanta, Georgia 30341, telephone 770/488-7490, fax 770/488-3635.

Due to programmatic issues that had to be resolved, the **Federal Register** notice is being published less than fifteen days before the date of meeting.

The Director, Management Analysis and Services office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for

both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 25, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0404]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for human tissue intended for transplantation.

**DATES:** Submit written or electronic comments on the collection of information by December 1, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Human Tissue Intended for Transplantation—21 CFR Part 1270 (OMB Control Number 0910-0302)—Extension

Under section 361 of the Public Health Service Act (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, through the use of human tissue for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet provisions intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed.

Section 1270.31(a) through (d) (21 CFR 1270.31(a) through (d)) require written procedures to be prepared and followed for the following steps: (1) All significant steps in the infectious disease testing process, (2) all

significant steps in reviewing the relevant medical record of the donor, (3) designating and identifying quarantined tissue, and (4) for prevention of infectious disease contamination or cross-contamination by tissue during processing. Section 1270.31(a) and (b) also require recording and justification of any deviation from the written procedures. Section 1270.33(a) (21 CFR 1270.33(a)) requires records to be maintained concurrently with the performance of each significant step in the procedures of infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records to be retained regarding the determination of the suitability of the donors and such records required under § 1270.21 (21 CFR 1270.21). Section 1270.33(h) requires all records be retained at least 10 years beyond the date of transplantation, distribution, disposition, or expiration of the tissue, whichever is latest. Section 1270.35 (21 CFR 1270.35) requires specific records be maintained to document the following outcomes: (1) The results and interpretation of all required infectious disease tests and results, (2) the identity and relevant medical records of the donor, (3) the receipt and distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. Based on information from FDA's Center for Biologics and Evaluation Research database system, the agency estimates that there are approximately 300 tissue establishments of which 166 are conventional tissue banks and 134 are eye tissue banks. Based on information provided by industry, there are an estimated total of 750,000 conventional tissue products and 94,186 eye tissue products recovered per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 20,000 donors of conventional tissue and 47,796 donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirement in part 1270 (21 CFR part 1270). Based on information provided by industry associations, 50 to 75 percent (average 63 percent) of the conventional tissue banks are members of AATB (166 X 63 percent = 105), and 99 percent of eye tissue banks are members of EBAA (134 X 99 percent = 133). Therefore, recordkeeping by these 238