

Dated: November 9, 1999.

Eric M. Meslin,

Executive Director, National Bioethics Advisory Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-00-08]

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, the Centers for Disease Control and Prevention is providing opportunity for public comment on proposed data collection 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) 639-7090.

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 for 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

1. HIV Prevention Programs in National/Regional Minority and Other Community Based Organizational Project Reports (0920-0249)—Reinstatement—National Centers for HIV, STD, and TB Prevention (NCHSTP)—CDC funds National/Regional Minority Organizations and Community Based Organizations to conduct HIV prevention programs. This data collection approves the submission of quarterly narrative reports for HIV

prevention programs developed by funded for National/Regional Minority Organizations and Community Based Organizations. These requires quarterly progress reports provided CDC with the necessary information to monitor program performance and accurately document activities that occur in these organizations funded under CDC.

Reports allow CDC to identify problems and technical assistance needs of grantees in a timely fashion and subsequently improve the effectiveness of project activities and progress toward national goals. They also assist CDC, by discerning and refining national goals and objectives in the prevention of HIV. The process of preparing quarterly reports is a valuable tool for examining program performance by assessing strengths and weaknesses in line with programmatic goals and national objectives. In addition these reports serve as technology transfer tools to identify what interventions work and can be duplicated to be used as a model for other national/regional minority and community based organizations.

The estimated annualized cost per respondent is \$231.60 for national and regional minority organizations and \$207.72 for community based organizations based.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per response	Total burden hours
NRMOS	32	3	4	384
CBOs	184	3	4	2,208
Total	2,592

Dated: November 9, 1999.

Nancy Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Fernald Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease

Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Fernald Health Effects Subcommittee.

Times and Dates: 1 p.m.-9 p.m., December 7, 1999. 8:30 a.m.-5 p.m., December 8, 1999.

Place: The Plantation, 9660 Dry Fork Road, Harrison, Ohio 45020. Telephone 513/367-5610.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide a forum

for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters To Be Discussed: Agenda items include presentations from the National Institute for Occupational Safety and Health (NIOSH) and the Agency for Toxic Substances and Disease Registry (ATSDR) regarding the progress of current studies. There will also be a presentation of results from research on cancer mortality among Fernald site workers due to radiation and chemical exposure.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Dr. David Pedersen, Health-Related Energy Research Branch, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, CDC, Robert A. Taft Laboratory, 4676 Columbia Parkway, M/S R-44, Cincinnati, Ohio 45226. Telephone 513/841-4400, Fax 513/841-4470.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 8, 1999.

Carolyn J. Russell,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Infectious Diseases: Meeting

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

Name: Board of Scientific Counselors, National Center for Infectious Diseases (NCID).

Times and Dates: 9 a.m.-5:30 p.m., December 2, 1999. 8:30 a.m.-2:30 p.m., December 3, 1999.

Place: CDC, Auditorium B, 1600 Clifton Road, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Board of Scientific Counselors, NCID, provides advice and guidance to the Director, CDC, and Director, NCID, in the following areas: program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

Matters to be Discussed: Agenda items will include:

1. NCID Update
2. Informatics
3. Chronic Fatigue Syndrome
4. NCID Research Agenda
5. Discussions
6. Vaccine Issues:
 - Rotavirus
 - Yellow Fever
7. Antimicrobial Resistance
8. Emergency Preparedness—Update
9. Outbreak Investigations—Update
 - Nipah virus
 - West Nile virus
10. Discussions and Recommendations

Other agenda items include announcements/introductions; follow-up on actions recommended by the Board May 1999; consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Diane S. Holley, Office of the Director, NCID, CDC, M/S C-20, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0078.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 8, 1999.

Carolyn J. Russell,

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. 99D-4487]

Medical Devices; Draft Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves." This guidance is neither final nor is it in effect at this time. This guidance describes the information needed to support an expiration date labeling claim for

powdered or powder-free, surgeon's or patient examination gloves. Expiration dating of medical gloves is voluntary at this time. FDA recommends that manufacturers, repackagers, or importers who add an expiration date labeling claim follow the enclosed recommended criteria and protocols for conducting testing described in this guidance.

DATES: Written comments concerning this draft guidance must be received by February 14, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the guidance document entitled, "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Written comments concerning this guidance must be submitted to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

SUPPLEMENTARY INFORMATION:

I. Background

It is estimated that millions of health care workers use medical gloves on a daily basis as a barrier against blood borne pathogens and microorganisms. The effective use of medical gloves as a barrier, however, is dependent upon the integrity of the glove material. Degradation of the glove material may occur when exposed to various types of manufacturing processes (e.g., chlorination) and/or environmental conditions.

In response to growing concerns regarding the use of natural rubber latex (NRL), the National Institute of Occupational Safety and Health recently issued a safety alert recommending the use of powder-free medical gloves as a means to reduce exposure to natural