

Place: CDC, Koger Center, Williams Building, Conference Rooms 1802 and 1805, 2877 Brandywine Road, Atlanta, Georgia 30341.

Status: Open to the public, limited only by the space available. The meeting rooms accommodate approximately 85 people.

Purpose: This workgroup advises CLIAC on issues related to Genetic Testing.

Matters to be Discussed: The workgroup will discuss and revise recommendations for general or specific Clinical Laboratory Improvement Amendments (CLIA) requirements for pre-analytic, analytic, and post-analytic components of genetic testing.

Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: John C. Ridderhof, Dr. P.H., Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NW Mailstop G-25, Atlanta, Georgia 30341, telephone 770/488-8076, FAX 770/488-8282.

Dated: June 26, 1998.

Carolyn J. Russell,

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

[FR Doc. 98-17917 Filed 7-6-98; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting

National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Laboratory Evaluation of Novel Personal Heat Strain Monitors in Young and Older Wearers of Protective Clothing.

Time and Date: 1 p.m.-3:30 p.m., July 21, 1998.

Location: NIOSH, CDC, Room H-203, 1095 Willowdale Road, Morgantown, WV 26505.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 35 people.

Purpose: Participants will provide NIOSH with their individual advice and comments regarding the technical and scientific aspects of the study protocol, A Laboratory Evaluation of Novel Personal Heat Strain Monitors in Young and Older Wearers of Protective Clothing, being conducted at NIOSH. Participants on the peer review panel will review the study protocol and provide individual advice on the conduct of this study. Viewpoints and suggestions from industry, labor, academia, other governmental agencies, and the public are invited.

Contact Person for Additional Information: Nina L. Turner, NIOSH, CDC, M/S 35, 1095 Willowdale Road, Morgantown, West Virginia, 26505-2888, telephone 304/285-5976.

Dated: June 30, 1998.

Carolyn J. Russell,

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

[FR Doc. 98-17916 Filed 7-6-98; 8:45 am]

BILLING CODE 4160-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0492]

ICI PLC; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that ICI PLC has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of N,N-bis (2-hydroxyethyl) alkyl (C₁₃-C₁₅) amine as an antistatic agent in polypropylene homo- and copolymers intended for contact with food.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4602) has been filed by ICI PLC, c/o ICI Surfactants, P.O. Box 8340, Wilmington, DE 19803-8340. The petition proposes to amend the food additive regulations in § 178.3130 *Antistatic and/or antifogging agents in food-packing materials* (21 CFR 178.3130) to provide for the expanded safe use of N,N-bis (2-hydroxyethyl) alkyl (C₁₃-C₁₅) amine as an antistatic agent in polypropylene homo- and copolymers intended for contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 17, 1998.

Linda M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98-17877 Filed 7-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Team Biologics; Workshop for Manufacturers of Licensed In Vitro Diagnostics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) is announcing the following workshop for the biologics industry: Team Biologics: Workshop for Manufacturers of Licensed In Vitro Diagnostics. The topics to be discussed include information for manufacturers of licensed in vitro diagnostics on team biologics, good manufacturing practices, and compliance and enforcement issues. Questions submitted by industry prior to the workshop will be addressed by FDA staff.

Date and Time: The workshop will be held on Friday, August 7, 1998, 8 a.m. to 5 p.m.

Location: The workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro, Bethesda, MD 20814, 301-657-6406.

Contact: Kathy A. Eberhart, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-49), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX 301-827-3079, e-mail "eberhart@cber.fda.gov".

Registration: Fax registration information (including name, title, firm name, address, telephone, and fax number) and questions to the contact person by Friday, July 24, 1998. There is no registration fee for the workshop. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Kathy A. Eberhart at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA has established a framework for a partnership between ORA and CBER called Team Biologics. This partnership will use the diverse skills and knowledge of both ORA and CBER staffs to focus resources on inspectional and compliance issues in the biologics area.

The goal of Team Biologics is to ensure the quality and safety of biological products and quickly resolve inconsistencies and bring products into compliance. It is designed to promote uniformity between CBER and the field and among FDA field components associated with inspections, policy implementation, and current good manufacturing practice interpretation.

In April 1998, the responsibility for inspecting manufacturers of licensed in vitro diagnostics was transferred to Team Biologics investigators. The purpose of this workshop is to provide an overview of the Team Biologics concept to this segment of regulated industry, share the agency's experience with Team Biologics' inspections of manufacturers of licensed in vitro diagnostics to date, and provide manufacturers with an overview of FDA's expectations under this program.

The agenda and any other relevant information will be available electronically via the Internet at "<http://www.fda.gov/cber/scireg.htm>".

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857,

approximately 15 working days after the workshop at a cost of 10 cents per page. FDA will videotape the workshop and copies of the tapes will also be made available through the Freedom of Information Office.

Dated: June 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-17878 Filed 7-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-96-6000]

Memorandum of Understanding Between the Food and Drug Administration and the Defense Alliance for Advanced Medical Terminology

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing

notice of a memorandum of understanding (MOU) between FDA and the Defense Alliance for Advanced Medical Terminology (DAAMT). The purpose of the MOU is to enable government agencies to exchange information and jointly pursue research endeavors related to medical device safety and effectiveness.

DATES: The agreement became effective October 17, 1996.

FOR FURTHER INFORMATION CONTACT:

Thomas B. Shope, Center for Devices and Radiological Health (HFZ-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3314, ext. 32.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of an MOU.

Dated: June 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

BILLING CODE 4160-01-F