DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

General Reorganization; Statement of Organization, Functions, and Delegations of Authority

Part E, Chapter E (Agency for Health Care Policy and Research), of the Statement of Organization, functions, and Delegations of Authority for the Department of Health and Human Service (61 FR 15955–58, April 10, 1996, and 62 FR 61511–12, November 18, 1997) is amended to reflect organizational changes within the Agency for Health Care Policy and Research (AHCPR). This action is necessitated by a reordering of Agency priorities and the need to more effectively align and utilize Agency resources. The principal organizational and functional changes required by this action involve:

A. Abolishing the Office of Planning and Evaluation, with certain functions being reassigned to other components in AHCPR;

B. Abolishing the Center for Information Technology, with a limited number of its functions absorbed by other components of the Agency;

C. Retitling the Office of Scientific Affairs to be more reflective of expanded functions, and;

D. Establishing a staff-level office within the Office of the Administrator to carry out the functions of the Center for Health Information Dissemination, which will subsequently be abolished by this action.

Other minor changes have been made consistent with this reorganization.

Under *Section E–10, Organization,* delete entries A. through M. and insert the following:

A. Immediate Office of the Administrator
B. Office of Management
C. Office of Policy Analysis
D. Office of Research Review, Education, and Policy
E. Office of Health Care Information
F. Center for Cost and Financing Studies
G. Center for Organization and Delivery Studies
H. Center for Outcomes and Effectiveness Research
I. Center for Primary Care Research
J. Center for Quality Measurement and Improvement
K. Center for Practice and Technology Assessment

Under *Section E–20, Functions,* delete the titles and statements for the *Office of Planning and Evaluation (EAB),* the *Office of Scientific Affairs (EAE),* the *Center for Health Information Dissemination (EF),* and the *Center for Information Technology (EG).*

Within the statement for the *Immediate Office of the Administrator (EA),* delete (2) and insert the following: ''(2) plans, directs, coordinates, and evaluates the Agency's research, training programs, and dissemination activities, including particular focus areas, such as special populations, initiatives, and administrative policies and procedures;''.

Within the statement for the *Office of Policy Analysis (EAC),* make the following changes:

Delete (6) and insert the following: ''(6) coordinates the legislative activities of the Agency including the development of legislative proposals and analysis of health legislative initiatives, and reports to Congress;''

Following (8), insert the following: ''(9) coordinates review and clearance of Department and other Federal policies and regulations; and'' and renumber the old (9) as (10).

Following the statement for the *Office of Policy Analysis (EAC),* insert the following:

Office of Research Review, Education, and Policy (EAE). Directs the scientific review process for grants and Small Business Innovation Research (SBIR) contracts, the assignment of applications to Agency Centers, manages Agency research training programs, and evaluates the scientific contribution of proposed and on-going research, demonstrations, and evaluations. Specifically: (1) directs the process for selecting, reviewing, and funding grants and reviewing SBIR contracts for scientific merit and program relevance; (2) assigns grant applications to Centers for administrative action; (3) manages the process for making funding decisions for grants; (4) directs Agency research training programs and implementation of the National Research Service Award authority; (5) manages the committee management and scientific integrity processes for the intramural and extramural programs of the Agency; (6) develops and coordinates clearance of peer review regulations, as required, policy notices and program announcements; (7) facilitates Agency-wide communication and coordination regarding extramural policy, planning, and analysis; and (8) represents the Agency in meetings with experts and organizations on issues related to the administration of the Agency's scientific programs.

Office of Health Care Information (EAF). Designs, develops, implements, and manages programs for disseminating the results of Agency activities. Specifically: (1) Communicates the results and significance of health services research and other AHCPR initiatives to the health care industry, health care providers, consumers and patients, policy makers, researchers, and the media with particular emphasis on communicating AHCPR initiatives in the ways each of these constituencies are most interested; (2) manages the editing, publication, and information distribution processes of the Agency, including Freedom of Information Act administration; (3) provides the administrative support for reference services and the distribution of technical information to Agency staff; (4) manages the public affairs activities of the Agency, Agency clearinghouse for responding to requests for information and technical assistance, and a program for consumer information about health care research findings; (5) directs a user liaison program to provide health care research and policy findings to Federal, State and local public officials, and other audiences as appropriate; (6) evaluates the effectiveness of Agency dissemination strategies and implements changes indicated by such evaluations; and (7) represents the Agency in meetings with Department and Public Health Service representatives on press releases, media events, and publication clearance.

All delegations and redelegations of authority to officers and employees of the Agency for Health Care Policy and Research which were in effect immediately prior to the effective date of this reorganization shall continue in effect pending further redelegation, provided they are consistent with this reorganization.

These changes are effective upon date of signature.

Dated: June 18, 1998.

John M. Eisenberg,

Administrator.

[FR Doc. 98–17923 Filed 7–6–98; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC): Meeting

Name: CLIAC, Workgroup on Genetic Testing.

Times and Dates: 8:30 a.m.–5 p.m., July 30, 1998; 8:30 a.m.–5 p.m., July 31, 1998.

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 (C_{13}-C_{15}) 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 (C_{13}-C_{15}) 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.