

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement No. 98043]

National Partnerships for Human Immunodeficiency Virus (HIV) Prevention; Notice of Availability of Funds for Fiscal Year 1998 Withdrawal

A notice of availability of funds for (FY) 1998 was published in the **Federal Register** on April 3, 1998, [63 FR 16555 through 16561]. The notice is hereby withdrawn. The agency will submit a notice of availability of funds at a later date.

Dated: April 7, 1998.

Arthur C. Jackson,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-9619 Filed 4-10-98; 8:45 am]

BILLING CODE 4163-18-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Chronic Fatigue Syndrome Coordinating Committee: 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: Chronic Fatigue Syndrome Coordinating Committee (CFSCC).

Time and Date: 8:30 a.m.-4 p.m., April 28, 1998. 9:30 a.m.-5 p.m., April 29, 1998.

Place: Hubert H. Humphrey Building, Rooms 703A and 800, #200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available. The meeting rooms will accommodate approximately 100 people.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card will need to provide a photo ID and must know the subject and room number of the meeting in order to be admitted into the building. Visitors must use the Independence Avenue entrance.

Purpose: The Committee is charged with providing advice to the Secretary, the Assistant Secretary for Health, and the Commissioner, Social Security Administration (SSA), to assure interagency coordination and communication regarding chronic fatigue syndrome (CFS) research and other related issues; facilitating increased

Department of Health and Human Services (HHS) and agency awareness of CFS research and educational needs; developing complementary research programs that minimize overlap; identifying opportunities for collaborative and/or coordinated efforts in research and education; and developing informed responses to constituency groups regarding HHS and SSA efforts and progress.

Matters To be Discussed: Agenda items will include the National Institutes of Health state of the art workshop regarding CFS in adolescents; updates from HHS agencies; CFS information and education; and CFSCC discussion of workshop regarding CFS in adolescents.

Agenda items are subject to change as priorities dictate.

Public comments will be received on the April 29, 1998, meeting for approximately 60 minutes. Public statements presented at this meeting should not be repetitive of previously submitted oral or written statements. Persons wishing to make oral comments should notify the contact person listed below no later than close of business on April 24, 1998. All requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. These comments will become a part of the official record of the meeting. Due to the time available, public comments will be limited to five minutes per person. Copies of any written comments should be provided at the meeting; please provide at least 100 copies.

Contact Person for More Information: Lisa Blake-DiSpigna, Executive Secretary, CDC, 1600 Clifton Road, NE, M/S C19, Atlanta, Georgia 30333, telephone 404/639-3227, fax 404/639-4138.

Dated: April 3, 1998.

Nancy C. Hirsch,

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

[FR Doc. 98-9618 Filed 4-10-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and

recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on April 27, 1998, 10:30 a.m. to 5 p.m., and April 28, 1998, 8 a.m. to 6 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Hany W. Demian, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 28, 1998, the committee will: (1) Discuss and make recommendations on a reclassification petition for Polymethylmethacrylate (PMMA) bone cement; (2) consider issues relating to the study and evaluation of bone growth stimulator devices as discussed in the draft guidance document entitled "Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices;" and (3) address scientific issues pertaining to investigations and marketing considerations of bone growth stimulators (e.g., inclusion/exclusion criteria, type of control(s), study endpoints, and length of followup). Single copies of the draft guidance document are available to the public by contacting the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1-800-638-2041, by faxing your request to 301-443-8818. The agency will publish in the near future a notice of availability which will include the web site.

Procedure: On April 27, 1998, from 10:30 a.m. to 11:30 a.m., and on April 28, 1998, from 8 a.m. to 6 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 20, 1998. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:45 a.m., on April 27, 1998, and between approximately 2:45 p.m. and 3:45 p.m., on April 28, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the

contact person before April 20, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On April 27, 1998, from 11:30 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

FDA regrets that it was unable to publish this notice 15 days prior to the April 27, 1998, Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 8, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-9704 Filed 4-9-98; 12:38 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0451]

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a proposed guide entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (the proposed guide)." The document provides guidance on good agricultural practices (GAP's) and good manufacturing practices (GMP's). The GAP's and GMP's are designed to

minimize microbial food safety hazards common to the growing, harvesting, packing, and transport of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (i.e., raw) form. This action is in response to the Presidential initiative to ensure the safety of imported and domestic fruits and vegetables. The proposed guide is intended to assist growers, packers, and other operators in continuing to improve the safety of domestic and imported produce.

DATES: Written comments by June 29, 1998.

ADDRESSES: Submit written comments on the proposed guide to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Submit written requests for single copies of the proposed guide entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" to Lou Carson, Center for Food Safety and Applied Nutrition, 200 C St. SW., rm. 3812, Washington, DC 20204, 202-260-8920. Send one self-adhesive address label to assist that office in processing your request. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the proposed guidance 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:

Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5916, FAX 202-260-9653, e-mail: jsaltsma@bangate.fda.gov, or Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-2975, FAX 202-205-4422, e-mail: msmith1@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

On October 2, 1997, the President announced the "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables" (fresh produce safety initiative). As part of the fresh produce safety initiative, the President directed the Secretary of Health and Human Services (DHHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue, within 1 year, guidance on GAP's and GMP's

for fresh fruits and vegetables. FDA is coordinating the effort for DHHS.

As part of this effort, FDA and USDA held a series of public meetings between November 17, 1997, and December 12, 1997, to provide the details on a broad approach on how to minimize microbial contamination through the control of water, manure, worker health and hygiene, field and facility sanitation, and transportation. A draft guide entitled "Working Draft: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables" (the working draft) was made available on FDA's World Wide Web (WWW) home page (<http://www.fda.gov>) and at each public meeting. The Fresh Produce Subcommittee of the National Advisory Committee for Microbiological Criteria for Food also reviewed and commented on sections of a working draft at the November 1997, meeting. Transcripts of these meetings and all comments received on the working draft of the proposed guide are on file in the Dockets Management Branch (address above) under the docket number appearing in brackets in the heading of this document and are accessible via the FDA home page on the WWW (<http://www.fda.gov/dockets/dockets.htm>).

With this notice, FDA is announcing the availability of the proposed guide. The proposed guide responds to comments received on the draft guidance document and represents the agencies' current thinking on strategies to minimize microbial hazards for fresh fruits and vegetables. The proposed guide does not create or confer any rights for or on any person and does not operate to bind FDA, USDA, or the public. An alternative approach may be used if such approach would effectively serve to reduce the microbial contaminants that could result in foodborne illnesses and if such approach satisfies applicable statutes and regulations. The proposed guide is being distributed for comment purposes, in accordance with the FDA's policy for Level 1 Good Guidance Practices documents as set out in the **Federal Register** of February 27, 1997 (62 FR 8961).

Because the guide is voluntary guidance, and not a regulation imposing binding requirements, FDA is not required to perform an economic impact analysis of the recommendations contained therein. However, the agency recognizes that, to reduce microbial hazards, the industry will want to select good agricultural and manufacturing practices that are most cost-effective, appropriate to their individual operations.