

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 26, 2001, 8:30 a.m. to 5:30 p.m., and on July 27, 2001, 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 26, 2001, the committee will hear presentations on the available safety and efficacy data for Aviron, Inc.'s cold adapted, live attenuated, trivalent influenza virus vaccine (FluMist™). On July 27, 2001, the committee will discuss the available data and the proposed indications for FluMist™.

Procedure: On July 26, 2001, from 10:15 a.m. to 5:30 p.m., and on July 27, 2001, from 8:30 a.m. to 3:30 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 July 8, 2001. On July 27, 2001, oral presentations will be held between approximately 9 a.m. and 10:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 8, 2001, 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 July 26, 2001, from 8:30 a.m. to 10:15 a.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)).

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

Dated: June 19, 2001.

Bonnie Malkin,

Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01-15912 Filed 6-25-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0232]

Medical Devices Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 1, 2001 (66 FR 29822). The document announced the availability of the draft guidance entitled "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff." The document published inadvertently omitting the address for the Dockets Management Branch. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy, Planning, and Legislation (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, June 1, 2001, in FR Doc. 01-13731, on page 29822, in the third column, correct the **ADDRESSES** caption to read:

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff" 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. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

Dated: June 19, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-15911 Filed 6-25-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-4019-N]

Medicare Program: Meeting of the Advisory Panel on Medicare Education—July 12, 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a)(1) and (a)(2) (Pub. L. 92-463), this notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) on July 12, 2001. This meeting is open to the public.

DATES: *The Meeting.* The meeting is scheduled for July 12, 2001, from 9 a.m. to 5 p.m., E.D.T.

Deadline for Presentations and Comments: July 5, 2001, 12 noon, E.D.T.

ADDRESSES: The meeting will be held at the Holiday Inn on the Hill, 415 New Jersey Avenue, NW., Washington, DC, 20001, (202) 638-1616.

FOR FURTHER INFORMATION CONTACT:

Nancy Caliman, Health Insurance Specialist, Partnership Development Group, Center for Beneficiary Services, Health Care Financing Administration, 7500 Security Boulevard, S2-23-05, Baltimore, MD 21244-1850, (410) 786-5052. Please refer to the HCFA Advisory Committees Information Line (1-877-449-5659 toll free)/(410-786-9379 local) or the Internet (<http://www.hcfa.gov/events/apme/homepage.htm>) for additional information and updates on committee activities, or contact Ms. Caliman via E-mail at APME@hcfa.gov. Press inquiries are handled through the HCFA Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION: Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary of the Department of Health and Human Services (the Secretary) the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7849) and approved the renewal of the charter on January 18, 2001. The Panel advises and makes recommendations to the Secretary and the Administrator of the Health Care Financing Administration (the Administrator) on opportunities for HCFA to optimize the effectiveness of the National Medicare Education Program and other HCFA programs that help Medicare beneficiaries understand Medicare and the range of Medicare options available with the passage of the Medicare+Choice Program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Diane Archer, J.D., President, Medicare Rights Center; David Baldrige, Executive Director, National Indian Council on Aging; Bruce Bradley, M.B.A., Director, Managed Care Plans, General Motors Corporation; Carol Cronin, Chairperson, Advisory Panel on Medicare Education; Joyce Dubow, M.U.P., Senior Policy Advisor, Public Policy Institute, AARP; Jennie Chin Hansen, Executive Director, On Lok Senior Health Services; Elmer Huerta, M.D., M.P.H., Director, Cancer Risk and Assessment Center, Washington Hospital Center; Bonita Kallestad, J.D., M.S., Mid Minnesota Legal Assistance; Steven Larsen, J.D., M.A., Maryland Insurance Commissioner, Maryland Insurance Administration; Brian Lindberg, M.M.H.S., Executive Director, Consumer Coalition for Quality Health Care; Heidi Margulis, B.A., Vice President, Government Affairs, Humana, Inc.; Patricia Neuman, Sc.D., Director,

Medicare Policy Project, Henry J. Kaiser Family Foundation; Elena Rios, M.D., M.S.P.H., President, National Hispanic Medical Association; Samuel Simmons, B.A., President and CEO, The National Caucus and Center on Black Aged, Inc.; Nina Weinberg, M.A., President, National Health Council; and Edward Zesk, B.A., Executive Director, Aging 2000.

The agenda for the July 12, 2001 meeting will include the following:

- Recap of the previous (April 26, 2001) meeting.
- HCFA update/issues.
- Role of the Social Security Administration in Medicare.
- Medicare education operating priorities for 2002.
- Medicare education budget 2003.
- Annual report of the Advisory Panel on Medicare Education.
- Public comment.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should contact Ms. Caliman by 12 noon, July 5, 2001. A written copy of the oral presentation should also be submitted to Ms. Caliman by 12 noon, July 5, 2001. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Caliman by 12 noon, July 5, 2001. The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodations should contact Ms. Caliman at least 15 days before the meeting.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 19, 2001.

Thomas A. Scully,

Administrator, Health Care Financing Administration.

[FR Doc. 01-15947 Filed 6-25-01; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Training and Technical Assistance; Cooperative Agreement Announcement

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds; Request for applications.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of fiscal year (FY) 2001 funds for an open competition for one cooperative agreement with a national organization for a total amount of \$200,000. The goal of the cooperative agreement is to assist people who work in Eligible Metropolitan Areas (EMAs) under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act to understand and put into action the requirements of the CARE Act as reauthorized in October 2000.

Program Purpose: The applicant will transfer knowledge and provide practical help to a diverse group of people working in HIV-related programs that are located in EMAs regarding the new legislative requirements of the CARE Act. Recipients will include administrative and direct service staff of State/local AIDS programs, State/local health departments, agencies funded by the CARE Act, other AIDS Service Organizations (ASO) and Community Based Organizations (CBO), members of CARE Act planning bodies, and consumers.

Program Requirements: Applicants must propose a plan that will help achieve the purpose through one or more of the following six program objectives. Each program objective directly relates to one of the legislative requirements of the new CARE Act.

(1) Increase the number of people with a history of homelessness, substance abuse, and correctional detention, who are members of Title I CARE Act Planning Councils, or regularly attend or actively participate in Planning Council meetings.

(2) Increase the ability of CARE Act administrators, planning bodies and care providers to identify the unmet needs of PLWH who are not in care, to bring them into care, and to keep them in care.

(3) Increase the number of formal linkages and referral agreements among providers of HIV social support services, HIV prevention services, and HIV care