

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]

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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.