

The current members of the Panel are: James L. Bildner, Chairman and Chief Executive Officer, Tier Technologies; Dr. Jane Delgado, Chief Executive Officer, National Alliance for Hispanic Health; Joyce Dubow, Senior Policy Advisor, Public Policy Institute, American Association of Retired Persons (AARP); Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Timothy Fuller, Executive Director, National Gray Panthers; John Graham IV, President and Chief Executive Officer, American Society of Association Executives; Dr. William Haggett, Senior Vice President, Government Programs, Independence Blue Cross; Thomas Hall, Chairman and Chief Executive Officer, Cardio-Kinetics, Inc.; David Knutson, Director, Health System Studies, Park Nicollet Institute for Research and Education; Brian Lindberg, Executive Director, Consumer Coalition for Quality Health Care; Katherine Metzger, Director, Medicare and Medicaid Programs, Fallon Community Health Plan; Dr. Laurie Powers, Co-Director, Center on Self-Determination, Oregon Health Sciences University; Dr. Marlon Priest, Professor of Emergency Medicine, University of Alabama at Birmingham; Dr. Susan Reinhard, Co-Director, Center for State Health Policy, Rutgers University and Chairperson of the Advisory Panel on Medicare Education; Dr. Everard Rutledge, Vice President of Community Health, Bon Secours Health Systems, Inc.; Jay Sackman, Executive Vice President, 1199 Service Employees International Union; Dallas Salisbury, President and Chief Executive Officer, Employee Benefit Research Institute; Rosemarie Sweeney, Vice President, Socioeconomic Affairs and Policy Analysis, American Academy of Family Physicians; and Bruce Taylor, Director, Employee Benefit Policy and Plans, Verizon Communications.

The agenda for the February 5, 2004, meeting will include the following:

- Recap of the previous (November 20, 2003) meeting.
- Centers for Medicare & Medicaid Services update/ Center for Beneficiary Choices update.
- Medicare Prescription Drug, Improvement and Modernization Act update.
- Public comment.
- Listening session with CMS leadership.
- Next steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic must submit a written copy of the oral presentation to Lynne Johnson, Health Insurance Specialist,

Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S2-23-05, Baltimore, MD 21244-1850 or by email at [1johnson3@cms.hhs.gov](mailto:1johnson3@cms.hhs.gov) no later than 12 noon, e.s.t., January 29, 2004. 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. Johnson by 12 noon, (e.s.t.), January 29, 2004. The meeting is open to the public, but attendance is limited to the space available.

**Special Accommodation:** Individuals requiring sign language interpretation or other special accommodations must contact Ms. Johnson at least 15 days before the meeting.

**Authority:** Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102-3). (Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: December 29, 2003.

**Dennis G. Smith,**

*Administrator (Acting), Centers for Medicare & Medicaid Services.*

[FR Doc. 03-32321 Filed 12-31-03; 11:38 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 2003M-0442, 2003M-0443, 2003M-0444, 2003M-0445, 2003M-0446, and 2003M-0447]**

### Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

### FOR FURTHER INFORMATION CONTACT:

Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

### SUPPLEMENTARY INFORMATION:

#### I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness were placed on the Internet from December 5, 2001, through September 30, 2003. There were

no denial actions during the period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE OCTOBER 1, 2001, THROUGH SEPTEMBER 30, 2003.

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP 000009/2003M-0442	Calypte Biomedical Corp.	Calypte HIV-1 Urine EIA	January 12, 2001
BP 010009/2003M-0443	Calypte Biomedical Corp.	Cambridge Biotech HIV-1 Urine Western Blot	June 21, 2001
BP 010001/2003M-0444	BioMérieux, Inc.	NucliSens HIV-1 QT	November 19, 2001
BP 000028/2003M-0445	Bayer Corp.	The VERSANT HIV-1 RNA 3.0 Assay (bDNA)	September 11, 2002
BP 010047/2003M-0446	OraSure Technologies, Inc.	OraQuick Rapid HIV-1 Antibody Test	November 7, 2002
BP-020066/2003M-0447	BioMérieux, Inc.	Vironstika HIV-1 Plus O Microelisa System	June 6, 2003

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cber/products.htm>.

Dated: December 29, 2003.

**Jesse Goodman,**

*Director, Center for Biologics and Research.*

[FR Doc. 04-132 Filed 1-5-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel, Immune Escape in Human Cancer: Mechanisms and Therapeutic Implications.

*Date:* January 19-21, 2004.

*Time:* 7 p.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott Shadyside/Oakland, 5308 Liberty Avenue, Pittsburgh, PA 15224.

*Contact Person:* Shakeel Ahmad, Phd, Scientific Review Administrator, Research Programs Review Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd., Bethesda, MD 20892, (301) 594-0114, [amads@mail.nih.gov](mailto:amads@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 30, 2003.

**Anna P. Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-180 Filed 1-5-04; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Dental & Craniofacial Research; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Dental and Craniofacial Research Council, January 20, 2003, 8:30 a.m. to January 20, 2003, 4 p.m., National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD, 20892 which was published in the **Federal**

**Register** on December 23, 2003, 68 FR 74246.

The actual meeting will be held on January 20, 2004, not on January 20, 2003. The meeting is partially closed to the public.

Dated: December 30, 2003.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-182 Filed 1-5-04; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2003-16796]

#### Secretarial Authorization for Certain Members and Employees of the U.S. Coast Guard to Serve on the Board of Control, Coast Guard Mutual Assistance

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice.

**SUMMARY:** The Commandant of the Coast Guard has authorized certain Coast Guard personnel to serve on the Board of Control of Coast Guard Mutual Assistance, a non-federal military-welfare entity. These personnel will provide coordination, oversight, and advice to the management of the Coast Guard's Mutual Assistance Program.

**FOR FURTHER INFORMATION CONTACT:** CDR William J. Ziegler, (202) 267-2998.

**SUPPLEMENTARY INFORMATION:** Under authority of 10 U.S.C. 1033 and 1589, the Commandant of the Coast Guard, as authorized by the Secretary of Homeland Security, under Department