

physician organization, one representative of a consumer organization, and one representative of the pharmaceutical manufacturing industry. The term of office is 4 years, except that initial appointments will be staggered to permit an orderly rotation of membership.

Nomination Procedures

Interested persons may nominate one or more qualified persons for membership on the advisory committee. Nominations shall state that the nominee is willing to serve as a member of the advisory committee and appears to have no conflict of interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Selection of a representative of a consumer organization is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for screening, interviewing, and recommending candidates for the agency's selection. Representatives of a consumer organization must possess appropriate qualifications to understand and contribute to the committee's work.

Selection of the member representing pharmaceutical manufacturing industry interests will be made in accordance with the advisory committee member selection process (21 CFR 14.80).

The NABP and the U.S.P. will be sent letters requesting nominations for their representatives on the advisory committee.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. App. 2), section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a), section 904 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394) as amended by the Food and Drug Administration Revitalization Act (Pub. L. 101-635), and 21 CFR part 14, relating to advisory committees.

Dated: March 3, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-6152 Filed 3-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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: Biological Response Modifiers 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 March 24, 1998, 8:30 a.m. to 5 p.m.

Location: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-21), 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 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss CellPro Inc.'s Ceparate® SC System for use in processing autologous peripheral blood stem cells. The committee will also hear short briefings on research programs in the Laboratory of Cellular Immunology and the Laboratory of Developmental Biology.

Procedure: On March 24, 1998, from 8:30 a.m. to 1:30 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 March 17, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 17, 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 March 24, 1998, from 1:30 p.m. to 3:45 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 discuss current investigational new drug application submissions under FDA review. On March 24, 1998, from 3:45 p.m. to 5 p.m., the meeting will be closed to review data of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of this information.

FDA regrets that it was unable to publish this notice 15 days prior to the March 24, 1998, Biological Response Modifiers Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Biological Response Modifiers 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: March 5, 1998.

Michael A. Friedman,

Deputy Commission for Operations.

[FR Doc. 98-6210 Filed 3-6-98; 12:21 pam]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Consumer Forum; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA) Office of Consumer Affairs (OCA) is announcing the second in a series of National Consumer Forums. The forums provide an opportunity for FDA to engage in an open dialogue with consumers and patient advocates on a variety of regulatory and consumer-oriented issues.

Date and Time: The meeting will be held on March 20, 1998, from 1:30 p.m. to 3:30 p.m.

Location: The meeting will be held at the Washington Plaza Hotel,

Washington Room, Thomas Circle, at Massachusetts Ave. & 14th St. NW, Washington, DC, Metro Stop: Blue or Orange line to McPherson Square, Red line to Farragut North.

Contact: Michael D. Anderson, Office of Consumer Affairs, (HFE-40), Food and Drug Administration, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, 301-827-4417, FAX 301-443-9767, E-mail: Manders1@oc.fda.gov.

Registration: Send registration information (including name, title, organization, address, telephone, and fax number) to the contact person by March 16, 1998.

If you need special accommodations due to a disability, please contact Michael D. Anderson at least 7 days in advance.

Supplementary Information: The purpose of the Forum is to provide an opportunity for consumers and patients to meet with FDA officials to express their views and concerns on regulatory and consumer protection policies and patient protection issues.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HF1-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: March 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-6079 Filed 3-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N-0453]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Human Tissue Intended for Transplantation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management

(HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 11, 1997 (62 FR 65277), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0302. The approval expires on February 28, 2001.

Dated: March 2, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-6081 Filed 3-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-2021-N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: December 1997 and January 1998

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

ACTION: Notice.

SUMMARY: One new proposal for a Medicaid demonstration project was submitted to the Department of Health and Human Services during the month of January 1998 under the authority of section 1115 of the Social Security Act. No proposals were received during the month of December 1997. No proposals were approved, disapproved or withdrawn during that time period. (This notice can be accessed on the Internet at <http://www.hcfa.gov/cmso/sect1115.htm>.)

COMMENTS: We will accept written comments on this proposal. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Gloria Smiddy, Center for Medicaid and State Operations, Health Care Financing

Administration, Mail Stop C3-18-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

FOR FURTHER INFORMATION CONTACT: Gloria Smiddy, (410) 786-7723.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the **Federal Register** (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the **Federal Register** with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to grant solicitation or other competitive process is reported as received during the month that such grants or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, Disapproved, and Withdrawn Proposals for the Months of December 1997 and January 1998

A. Comprehensive Health Reform Programs

1. New Proposal

The following comprehensive health reform proposal was received during the month of January 1998.

Demonstration Title/State: BadgerCare/Wisconsin.

Description: The State submitted a proposal that would use a combination of title XIX and title XXI funding to ensure access to health care for all children and parents in uninsured families with incomes below 185