

applications, but also indicates procedural and other information about the meeting.

Dated: May 15, 1998.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 98-13478 Filed 5-15-98; 4:22 pm]

BILLING CODE 6210-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Health Care Policy and Research

#### Meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation

**AGENCY:** Agency for Health Care Policy and Research, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation.

**DATES:** The meeting will be held on Friday, June 5, 1998 from 8:30 a.m. to 4 p.m.

**ADDRESSES:** The meeting will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Nancy Foster, Coordinator of the Advisory Council at the Agency for Health Care Policy and Research 2101 East Jefferson Street, Suite 502, Rockville, Maryland 20852, (301) 594-1349 ext. 1307.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Linda Reeves, Assistance Administrator for Equal Opportunity, AHCP, on (301) 594-6665 ext. 1055 no later than May 22, 1998.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Purpose**

The Council provides advice to the Secretary and the Administrator, Agency for Health Care Policy and Research (AHCP), on matters related to AHCP activities to enhance the quality, appropriateness, and effectiveness of health care services and access to such services through scientific research and the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services. The Council is composed of members of the public appointed by the Secretary and Federal ex-officio members. The

Council will be chaired by Harold S. Luft, Ph.D.

##### **II. Agenda**

On Friday, June 5, 1998, the meeting will begin at 8:30 a.m., with the call to order by the Council Chairman. The Administrator, AHCP, will update the status of current Agency programs and initiatives. The Council will then discuss key issues in dissemination of research findings to promote their use, ethical aspects of using public funds for the development of products that will be marketed commercially, and future directions for research on quality, health economics, and primary care.

The meeting will adjourn at 4:00 p.m. Agenda items are subject to change as priorities dictate.

Dated: May 14, 1998.

**John M. Eisenberg,**

*Administrator.*

[FR Doc. 98-13396 Filed 5-19-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0056]

#### List of Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a list entitled "List of Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population" (hereinafter referred to as "the list"). This is a list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The list is being published under new statutory requirements of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). The purpose of the list is to identify certain drugs for which certain information is necessary to determine if an approved drug can be used safely and effectively in the pediatric population.

**DATES:** Submit written comments on the procedure and criteria used to develop the list at any time.

**ADDRESSES:** Submit written comments 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 list to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573. Send one self-addressed adhesive label to assist that office in processing your request. Single copies of the list may also be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), or by calling the CBER Voice Information System at 1-800-835-4709, or 301-827-1800. Copies of the list may be obtained from CBER's FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the list.

#### **FOR FURTHER INFORMATION CONTACT:**

Khyati N. Roberts, Center for Drug Evaluation and Research (HFD-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779, FAX 301-594-5493, e-mail robertsk@cder.fda.gov, or

David W. Feigal, Center for Biologics Evaluation and Research (HFM-6), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0376, FAX 301-827-0440, e-mail feigal@cber.fda.gov.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On November 21, 1997, President Clinton signed into law the Modernization Act (Pub. L. 105-115). Section 111 of the Modernization Act (21 U.S.C. 355A(b)) requires FDA, after consultation with experts in pediatric research, to develop, prioritize, and publish a list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. Inclusion of a drug on the list does not necessarily mean that the drug is entitled to pediatric exclusivity.

FDA developed a draft list in consultation with experts in pediatric research, trade organizations, and other interested persons, and made the draft list available for public comment (see 63 FR 12815, March 16, 1998). After consideration of comments on the draft list, FDA is publishing the list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population and announcing its availability through this notice.