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, AHCPR, 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 (AHCPR), on matters related to AHCPR 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, AHCPR, 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]

BILLING CODE 4160–90–M

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.

II. Procedure for Updating the List

The Modernization Act also requires FDA to update the list annually. FDA plans to update the list regularly and at least annually. Individuals desiring to comment on the procedure and criteria used to develop the list may submit at any time written comments identified with the docket number found in brackets in the heading of this document. Persons seeking to add a particular drug to the priority section of the list or to have a drug removed from the priority section of the list may submit to the agency a citizen petition that complies with the requirements of 21 CFR part 10. At its discretion, the agency may consult with a sitting advisory committee, which may include pediatric research experts, before determining whether to include a drug on or remove a drug from the list.

III. Electronic Access

Persons with access to the Internet may obtain the list and all updated versions of the list by using the World Wide Web (WWW). For WWW access, connect to CDER at http://www.fda.gov/cder/pediatric or to CBER at http://www.fda.gov/CBER/publications.htm.

IV. Request for Comments

Interested persons may submit at any time to the Dockets Management Branch (address above) written comments regarding the procedure and criteria used to develop the list. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The list and received comments will be available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday. Received comments will be considered in determination whether further revision of the list is warranted.

Dated: May 13, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–13554 Filed 5–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Addition of Routine Uses to an Existing System of Records

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notification of an addition of routine uses to an existing system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing a proposal to add three new routine uses for the records in System of Records 09–15–0056, National Vaccine Injury Compensation Program (VICP), BHPr/HRSA/HHS. HRSA proposes to specify the categories of records in the system, and to expand the list of routine use in record disclosures to include disclosures for research purposes, disclosures to annuity brokers, and disclosures to employees of life insurance companies for the purposes of providing benefits to recipients under the VICP.

DATES: HRSA invites interested parties to submit comments on the addition of new routine uses on or before June 19, 1998. The HRSA/VICP will adopt the new routine uses without further notice 30 days after the date of publication, unless HRSA receives comments which would result in a contrary determination.

ADDRESSES: Please address comments on the altered system of records to the Health Resources and Services Administration (HRSA) Privacy Act Officer, Department of Health and Human Services, 5600 Fishers Lane, Room 14A–20, Rockville, Maryland 20857, telephone (301) 443–3780. This is not a toll-free number.

FOR FURTHER INFORMATION CONTACT: Director, Division of Vaccine Injury Compensation, BHPr/HRSA, Room 8A–35, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–6593. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The routine use changes proposed are to expand the ''Routine Uses of Records'' to specify conditions for approving access to the system of records for research purposes.

Access to the system is limited to authorized users only. Stringent physical and procedural safeguards are in place to protect information.

The alteration of this system will have a minimal effect on an individual's privacy and should not affect personal rights. The information gathered for research purposes or benefit payment purposes will not be disclosed publicly in identifiable form.

Disclosure of information from this system of records may provide important information about vaccine safety, benefit-payment trends or the VICP.

The following notice is written in the present, rather than the future tense, to avoid the unnecessary expenditure of public funds to republish the notice after the routine use has become effective.

Dated: May 11, 1998.

Claude Earl Fox,

Acting Administrator.

Add to Routine Uses of Records Maintained in the System:

7. A record may be disclosed to annuity brokers and to employees of life insurance companies for the purposes of obtaining financial advice and for the purchase of contracts to provide benefits to recipients of benefits under the Program. Organizations to which information is disclosed for this use will be required to maintain Privacy Act safeguards with respect to such records.

8. A record may be disclosed to contractors for the purpose of providing medical review, analysis and determination as to whether petitions meet the medical requirements for compensation. Contractors will be required to maintain Privacy Act safeguards with respect to such records.

9. A record may be disclosed for a research purpose when the Department:

(A) Has determined that the disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(B) Has determined that the research purpose:

(1) Is consistent with the purpose for which the program was formed, which includes but is not limited to evaluating the safety of vaccines covered under the Program,

(2) Cannot be reasonably accomplished with information in statistical form, and must be provided in an identifiable form to accomplish the research purpose, and

(3) Warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(C) Has required the recipient to:

(1) Establish reasonable administrative, technical and physical safeguards to prevent unauthorized use or disclosure of the record,

(2) Remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and

(3) Make no further use of the record except: