This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Allergenic 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 April 7, 2005, from 8:30 a.m. to 4 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail Dapolito or Jane Brown, 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 3014512388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 7, 2005, the committee will discuss a proposed strategy for the reclassification of Class IIIA allergenic products. The committee will also receive an update of the FDA Critical Path Initiative.

Procedure: 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 31, 2005. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 12:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 31, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 2, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–4484 Filed 3–7–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Resources and Services Administration (HRSA); Request for Public Comment on a HRSA Commissioned Report: Newborn Screening: Toward a Uniform Screening Panel and System

SUMMARY: The changing dynamics of emerging technology, and the complexity of genetics require an assessment of the state of the art in newborn screening and a perspective on the future directions such programs should take. In 1999, the American Academy of Pediatrics Newborn Screening Task Force recommended that ''HRSA should engage in a national process involving government, professionals, and consumers to advance the recommendations of this Task Force and assist in the development and implementation of nationally recognized newborn screening system standards and policies.'' In response to this need, pursuant to 42 U.S.C. 701(a)(2), the Maternal and Child Health Bureau (MCHB) of HRSA commissioned the American College of Medical Genetics (ACMG) to conduct an analysis of the scientific literature on the effectiveness of newborn screening and gather expert opinion to delineate the best evidence for screening specified conditions and develop recommendations focused on newborn screening, including but not limited to the development of a uniform condition panel. It was expected that the analytical endeavor and subsequent recommendations be based on the best scientific evidence and analysis of that evidence. ACMG was specifically asked to develop recommendations to address:

- A uniform condition panel (including implementation methodology);
- Model policies and procedures for State newborn screening programs (with consideration of a national model);
- Model minimum standards for State newborn screening programs (with consideration of national oversight);
- A model decision matrix for consideration of State newborn screening program expansion; and
- The value of a national process for quality assurance and oversight.

The ACMG report is a response to the HRSA/MCHB request. The ACMG report, Newborn Screening: Toward a Uniform Screening Panel and System is available at *http://mchb.hrsa.gov/screening*.

In the report, 29 conditions were identified as primary targets or core panel conditions for screening; an additional 25 conditions were listed as conditions that could be identified in the course of screening for core panel conditions. Many of these 25 additional conditions are included in the differential diagnosis of the conditions including in the primary target list. With additional screening, an improvement in the infrastructure for appropriate follow-up and management throughout the lives of children who have been identified as having one of these rare conditions will be needed. A cost analysis for the State of California indicates newborn screening is beneficial to patients and may have some net costs or net savings over time depending on assumptions of expected lifetime costs of medical care.

HRSA is now seeking public comments on the report and its recommendations.

DATES: The public is encouraged to submit written comments on the report and its recommendations within 60 days of publication of this **Federal Register** notice.

ADDRESSES: The following mailing address should be used: Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, 18A–19, Rockville, MD 20857. HRSA/MCHB's facsimile number is 301–443–8604. Comments can also be sent via e-mail to *screening@hrsa.hhs.gov*. All public comments received will be available for public inspection at MCHB/HRSA's office between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Questions about this request for public comment can be directed to Dr. Michele Lloyd-Puryear, MD, PhD, by e-mail (*screening@hrsa.hhs.gov*). The report will be posted on HRSA/MCHB's Web site at *http://mchb.hrsa.gov/screening*.

Dated: March 2, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–4481 Filed 3–7–05; 8:45 am]

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