to pay the deductibles and coinsurance for dually-eligible beneficiaries.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 9, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 29, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–28251 Filed 11–4–10; 2:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: January 27, 2011, 8:30 a.m. to 5 p.m. January 28, 2011, 8:30 a.m. to 3:30 p.m.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration Web site at *http://altarum.cvent.com/event/SACHDNC012011.* The registration deadline is Tuesday, January 25, 2011. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations should indicate their needs on the registration Web site. The deadline for special accommodation requests is Friday, January 21, 2011. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator at *conferences@altarum.org.*

Purpose: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. The Advisory Committee also provides advice and recommendations concerning the grants and projects authorized under the Public Health Service Act, 42 U.S.C. 300b–10, (Heritable Disorders Program) as amended in the Newborn Screening Saves Lives Act of 2008.

Agenda: The meeting will include: (1) Presentations from the following Advisory Committee workgroups: Communications, Health Information Technology, and Evidence Review; (2) a report from a National Survey of Recent and Prospective Mothers about Newborn Screening; and (3) presentations on the continued work and reports of the Advisory Committee's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training. Proposed Agenda items are subject to change as priorities dictate. You can locate the Agenda, Committee Roster and Charter, presentations, and meeting materials at the home page of the Advisory Committee's Web site at *http://www.hrsa.gov/heritabledisorderscommittee/.*

Public Comments: Members of the public can present oral comments during the public comment periods of the meeting, which are scheduled for both days of the meeting. Those individuals who want to make a comment are requested to register online by Tuesday, January 25, 2011, at *http://altarum.cvent.com/event/SACHDNC012011.* Requests will contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The list of public comment participants will be posted on the Web site. Written comments should be e-mailed via e-mail no later than Tuesday, January 25, 2011, for consideration. Comments should be submitted to Maureen Ball, Meetings Coordinator, Conference and Meetings Management, Altarum Institute, 1200 18th Street, NW., Suite 700, Washington, DC 20036, *telephone:* 202 828–5100; *fax:* 202 785–3083, or *e-mail: conferences@altarum.org.*

Contact Person: Anyone interested in obtaining other relevant information should write or contact Alaina M. Harris, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0721, *aharris@hrsa.gov.* More information on the Advisory Committee is available at *http://mchb.hrsa.gov/heritabledisorderscommittee.*

Dated: November 2, 2010.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–28188 Filed 11–8–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0369]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6464, Silver Spring, MD 20993–0002, 301–796–0700; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to or has agreed to conduct by requiring the applicant to submit a report annually providing information