

requests the hearing, making findings and conclusions, and denying a hearing. If a hearing is requested and is justified by the sponsor's response to this notice, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will begin will be issued.

All submissions under this notice shall be filed in two copies. Except for information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512(e) (21 U.S.C. 360b(e))) and under authority delegated to the Director, Center For Veterinary Medicine (21 CFR 5.84).

Dated: May 20, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-14103 Filed 5-27-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Pulmonary-Allergy Drugs and Endocrinologic and Metabolic Drugs Advisory Committees; 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). The meeting will be open to the public.

Name of Committees: Joint meeting of the Pulmonary-Allergy Drugs and the Endocrinologic and Metabolic Drugs Advisory Committees.

General Function of the Committees: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on July 30, 1998, 8 a.m. to 5 p.m., and on July 31, 1998, 8 a.m. to 3:45 p.m.

Location: Bethesda Marriott Hotel, Grand Ballroom, 5151 Pooks Hill Rd., Bethesda, MD.

Contact Person: Leander B. Madoo or Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory

Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 12545 and 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 30, 1998, the committees will: (1) Discuss the impact of orally inhaled and intranasal corticosteroids on growth in children, (2) hear from invited experts regarding the process of normal growth and development in children and how various factors including corticosteroids may impact on it, and (3) review examples from industry of completed "growth studies" testing the various inhaled and intranasal corticosteroid drug products. On July 31, 1998, the agency will: (1) Present the proposed "class labeling" for inhaled and intranasal corticosteroid drug products, (2) review the data which support it, and (3) lead a general scientific discussion among all meeting participants to reach a consensus concerning appropriate labeling for these products and recommendations for the design and conduct of future clinical trials which assess growth.

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 July 23, 1998. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4:30 p.m., on July 30, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 23, 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.

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

Dated: May 20, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-14106 Filed 5-27-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Healthy Start Initiative—Phase II Limited Competition for the Mississippi Delta

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of availability of funds for a limited competition for the ten counties of Mississippi known as the Mississippi Delta.

SUMMARY: The HRSA announces the availability funds in fiscal year 1998 for a single cooperative agreement for the replication of the Healthy Start Initiative (HSI) Phase II within the ten counties of Mississippi known as the Mississippi Delta. The Healthy Start Initiative is a program of projects which, since FY 1991, has developed and implemented community-based strategies to reduce infant mortality in areas with a high incidence of infant mortality. The purpose of Healthy Start-Phase II is to operationalize successful infant mortality reduction strategies developed during the demonstration phase and to launch Healthy Start projects in new rural and urban communities (i.e., communities currently without a Healthy Start Initiative-funded project). Within the HRSA, the Healthy Start Initiative is administered by the Maternal and Child Health Bureau (MCHB). This cooperative agreement for Healthy Start-Phase II in the Mississippi Delta will be made under the program authority of Section 301 of the Public Health Service Act. Funds for this award were appropriated under Public Law 104-208.

To continue Healthy Start efforts to meet critical maternal and child health needs in the Mississippi Delta, public and nonprofit private organizations serving the following counties in the Mississippi Delta—Humphries, Holmes, Leflore, Bolivar, Quitman, Sunflower, Tallahatchie, Washington, Cohoma, and Tunica—are encouraged to apply. Applicants must provide services to all ten counties. Only one applicant organization will be funded.

The project period is three years, subject to continuing availability of funds.

ADDRESSES: Interested parties may contact the HRSA Grants Application Center for an application package. Requests should specify the Healthy Start Initiative—Phase II limited competition within the Mississippi Delta (CFDA #93.926b). The Center may