recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 19 and 20, 2001, 8 a.m. to 5 p.m.

Location: CDER Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD. Parking and seating is limited.

Contact: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776 or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 19, 2001, the committee will discuss new drug application (NDA) 21–239, Aslera® (prasterone, Genelabs Technologies, Inc.) for improvement in disease activity and/or its symptoms in women with mild to moderate systemic lupus erythematosus (SLE) and reduction of corticosteroid requirements in women with mild to moderate SLE.

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 April 13, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 13, 2001, 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.

Closed Committee Deliberations: On April 20, 2001, from 8 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

Dated: March 16, 20001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–7183 Filed 3–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; 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 Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs 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 24, 2001, 8 a.m. to 4 p.m.

Location: Best Western Washington Gateway Hotel, The Ballroom, 1251 West Montgomery Ave., Rockville, MD.

Contact: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: at SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss parameters used for extrapolation from the adult to the pediatric setting in the hematological malignancies of leukemia and lymphoma.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 17, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 17, 2001, 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: March 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–7185 Filed 3–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science; 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 Committee: Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science.

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 May 3, 2001, 8:30 a.m. to noon.

Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact: Nancy Chamberlin or Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: CHAMBERLINN@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee meeting will discuss strategies to identify promising areas of nonclinical scientific research to develop biomarkers and/or other evolving molecular technologies to identify or predict: (1) Drug-induced cardiac tissue injury, and (2) drug-induced vasculitis.

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 April 20, 2001. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Time allotted for

each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 20, 2001, 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: March 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–7181 Filed 3–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration Advisory Committee; 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 Committee: Science Board to the Food and Drug Administration.

General Function of the Committee: The board shall provide advice primarily to the agency's Senior Advisor for Science, and as needed, to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, formulating an appropriate research agenda, and upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on April 13, 2001, 9 a.m. to 4:30 p.m.

Location: 5630 Fishers Lane, rm. 1066, Rockville, MD.

Contact: Susan M. Bond, Office of Science Coordination and Communication (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12603. Please call the Information Line for up-to-date information on this meeting.

Agenda: Open committee discussion, 8:30 a.m. to 1 p.m.; open public hearing, 1 p.m. to l:30 p.m.; open committee discussion, 1:30 p.m. to 4:30 p.m. The board will hear and discuss programmatic peer review for the FDA's Center for Devices and Radiological Health. The committee will also discuss: (1) The FDA's Office of Women's Health research plan; (2) an overview of tissue and tissue engineered products; and (3) strategies to meet scientific workforce challenges.

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 April 6, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 6, 2001, 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: March 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–7184 Filed 3–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–00–8002]

Memorandum of Understanding Between the Food and Drug Administration, the Department of Agriculture, and the University of Puerto Rico

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration, the Department of Agriculture, and the University of Puerto Rico. The purpose is to establish a framework for collaboration on mutually agreed upon activities in scientific and regulatory areas.

DATES: The agreement became effective December 7, 2000.

FOR FURTHER INFORMATION CONTACT: Maritza Colon-Pullano, Office of the Commissioner (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4553.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: March 19, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

BILLING CODE 4160–01–S