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 November 17, 2003, from 8:30 a.m. to 5:30 p.m.; and on November 18, 2003, from 8:30 a.m. to 1:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, 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, or e-mail: *SCHARENH@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: On November 17, 2003, the subcommittee will discuss: (1) Quantitative analysis using exposure-response: Proposal for End-of-Phase2A (EOP2A) meeting and use of clinical trial simulation for PK-QT study design; and (2) pediatric decision tree: Examples for applying the pediatric decision tree. On November 18, 2003, the subcommittee will discuss the pediatric decision tree: (1) Use of clinical trial simulation in pediatric population pharmacokinetics study design; (2) drug interactions; and (3) pharmacogenetics: Integration into new drug development.

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 November 6, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon on November 17, 2003, and 12:30 p.m. and 1 p.m. on November 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2003, 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 Hilda Scharen 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: October 2, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–25446 Filed 10–7–03; 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; 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: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 6, 2003, 8 a.m. to 4:30 p.m.

Location: Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact Person: Jan Johannessen, Office of the Commissioner, Food and Drug Administration, HF–33, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, *jjohannessen@fda.gov*, 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: The Board will hear about and discuss FDA's Food Security Program.

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 October 22, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 22, 2003, 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.

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

Dated: October 3, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–25555 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0434]

Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment.'' This guidance describes how the Food and Drug Administration (FDA) will assess its performance in the premarket approval application (PMA) program relative to the goals that accompany the authorization of medical device user fees. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).