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.

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 Jan Johannessen 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 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).

**DATES:** Submit written or electronic comments on this guidance at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:**

*For Device Issues*: Thinh Nguyen, CDRH (HFZ–402), 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

*For Biologics Issues*: Sayah Nedjar, Center for Biologics Evaluation and Research (CBER) (HFM–380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3524.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), signed into law on October 26, 2002, allows FDA to assess user fees for certain premarket reviews. Performance goals, existing outside of the statute, accompany the authorization of medical device user fees. These goals represent a realistic projection of what FDA's CDRH and CBER offices can accomplish with industry cooperation.

The guidance describes premarket review cycle and decision actions and goals for original PMAs, original expedited PMAs, panel-track supplements, and 180-day PMA supplements. Although it was not feasible to obtain comments before issuing the guidance due to tight statutory deadlines, in accordance with this agency's GGP procedures, FDA will accept comments on the guidance at any time.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP regulation (21 CFR 10.115). The guidance represents the agency's current thinking on PMA review cycle and decision actions and performance goals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

To receive ''FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment ''by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1218) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

## IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910–0231).

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

To receive ''FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment ''by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1218) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Dated: September 30, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–25447 Filed 10–7–03; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[USCG–2003–16200]**

### National Boating Safety Activities: Funding for National Nonprofit Public Service Organizations

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Coast Guard seeks applications for fiscal year 2004 grants and cooperative agreements from national, nongovernmental, nonprofit, public service organizations. These grants and cooperative agreements would be used to fund projects on various subjects promoting recreational boating safety on the national level. This notice provides information about the grant and cooperative agreement application process and some of the subjects of particular interest to the Coast Guard.

**DATES:** Application packages may be obtained on or after October 8, 2003. Proposals for the fiscal year 2004 grant