

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science. This meeting was announced in the **Federal Register** of October 4, 2004 (69 FR 59238). The amendment is being made to reflect changes in the *Agenda* and *Location* portions of the document. There are no other changes.

#### FOR FURTHER INFORMATION CONTACT:

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, FAX: 301-827-6776, e-mail: [SCHARENh@cder.fda.gov](mailto: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.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 4, 2004, FDA announced that a meeting of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science would be held on November 3 and 4, 2004. On page 59238, in the third column, the *Location* and *Agenda* portions of the meeting are amended to read as follows:

*Location:* Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

*Agenda:* On November 3, 2004, the subcommittee will address the following issues: (1) Receive topic updates for ongoing FDA activities previously presented to the subcommittee; (2) discuss and provide comments on the evidence for updating labels of approved drugs to include integrating pharmacogenetic, pharmacokinetic, and prognostic biomarkers for the purpose of optimizing therapeutic response and reducing risks of toxicity, with CAMPTOSAR (irinotecan hydrochloride), by Pfizer Inc., as an example; and (3) discuss and provide comments on metabolism- and

transporter-based drug-drug interactions included as recommendations in a draft guidance for industry being prepared by FDA. On November 4, 2004, the subcommittee will discuss and provide comments on a new critical path project related to general aspects of the transition of biomarkers to surrogate endpoints, with a focus on planning and process, rather than on specific biomarkers or surrogate endpoints.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 14, 2004.

**Sheila Dearybury Walcott,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-23626 Filed 10-21-04; 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:* The Board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner 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, on formulating an appropriate research agenda, and on 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 November 5, 2004, 8 a.m. to 5 p.m.

*Location:* 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

*Contact Person:* Jan Johannessen, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, [jjohannessen@fda.gov](mailto:jjohannessen@fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512603. Please call the

Information Line for up-to-date information on this meeting.

*Agenda:* The Board will hear about and discuss: (1) An update on the FDA Critical Path Initiative (<http://www.fda.gov/oc/initiatives/criticalpath/>), including an overview of docket submissions, current status, reports on related activities (Medical Technology Innovation Task Force and Foods Critical Path White Paper), and future plans; (2) FDA's final report on pharmaceutical current good manufacturing practices ([http://www.fda.gov/cder/gmp/gmp2004/GMP\\_finalreport2004.htm](http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm)); and (3) an internal peer review of the Office of Regulatory Affairs' pesticide program, including plans for the establishment of a Science Board subcommittee to conduct an external program peer review.

*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 29, 2004. 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 29, 2004, 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 14, 2004.

**Sheila Dearybury Walcott,**

*Associate Commissioner for External Relations.*

[FR Doc. 04-23625 Filed 10-21-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting: