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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology;

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: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

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 July 22 and 23, 2008, from 8:30 a.m. to 5 p.m.

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

Contact Person: Diem-Kieu Ngo, 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: *Diem.Ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. Please call the Information Line for

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up to date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 22, 2008, the committee will do the following: (1) Receive presentations from the Office of Pharmaceutical Science (OPS) and discuss current thinking on issues pertaining to the use of nanotechnology in drug manufacturing, drug delivery, or drug products, and (2) receive an update from OPS, discuss, and make comments on current strategies and directions for the testing of lead in pharmaceutical products.

On July 23, 2008, the committee will do the following: (1) Receive and discuss presentations from the Office of Generic Drugs (OGD) on the bioequivalence methods for locally acting drugs that treat gastrointestinal (GI) conditions, (2) receive and discuss presentations from OGD on the use of inhaled corticosteroid dose-response as a means to establish bioequivalence of inhalation drug products, and (3) receive and discuss presentations from OPS on the drug classification of orally disintegrating tablets (ODT) as a separate dosage form, and the need for subsequent guidance on expectations and recommendations that would be required for applications proposing the dosage form.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory

committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

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 on or before July 8, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Those desiring to make formal oral presentations should notify the contact person 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 on or before June 30, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 1, 2008.

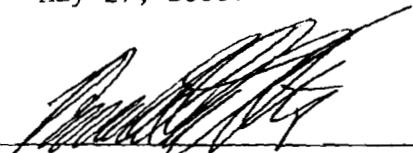
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: 5/27/08
May 27, 2008.



Randall W. Lutter,
Deputy Commissioner for Policy.

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