

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier N. Hawkins

Food and Drug Administration

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: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Dates and Time: The meeting will be held on October 21, 2002, from 8:30 a.m. to 5 p.m. and October 22, 2002, from 8:30 a.m. to 5 p.m.

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

Contact Person: Kathleen Reedy, 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: REEDYK@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 October 21, 2002, the committee will: (1) Receive summary reports and provide direction for the Nonclinical Studies Subcommittee and

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the Process Analytical Technologies Subcommittee; (2) receive updates on risk-based chemistry manufacturing control review and blend uniformity; and (3) discuss and provide comments on regulatory issues related to crystal habits—polymorphism. On October 22, 2002, the committee will: (1) Discuss and provide direction for future subcommittee—Good Manufacturing Practices/Manufacturing Subcommittee; and (2) discuss manufacturing issues; sterile drug products produced by aseptic processing.

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 14, 2002. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:45 p.m. on October 21, 2002, and 1 p.m. and 2 p.m. on October 22, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 14, 2002, 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.

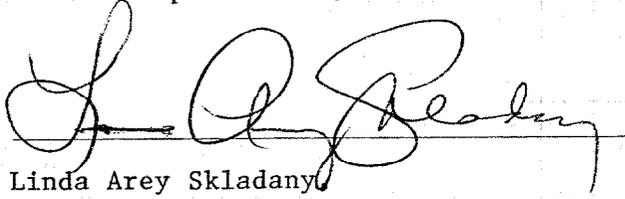
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Kathleen Reedy 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: *Sept 22, 2002*
September 22, 2002.



Linda Arey Skladany
Senior Associate Commissioner for
External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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**CERTIFIED TO BE A TRUE
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Lawn P. Hawkins