

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

**Manufacturing Subcommittee of the 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: Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

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

Date and Time: The meeting will be held on July 20 and 21, 2004, from 8:30 a.m. to 5 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, 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 3014512539. Please call the Information Line for up-to-date information on this meeting.

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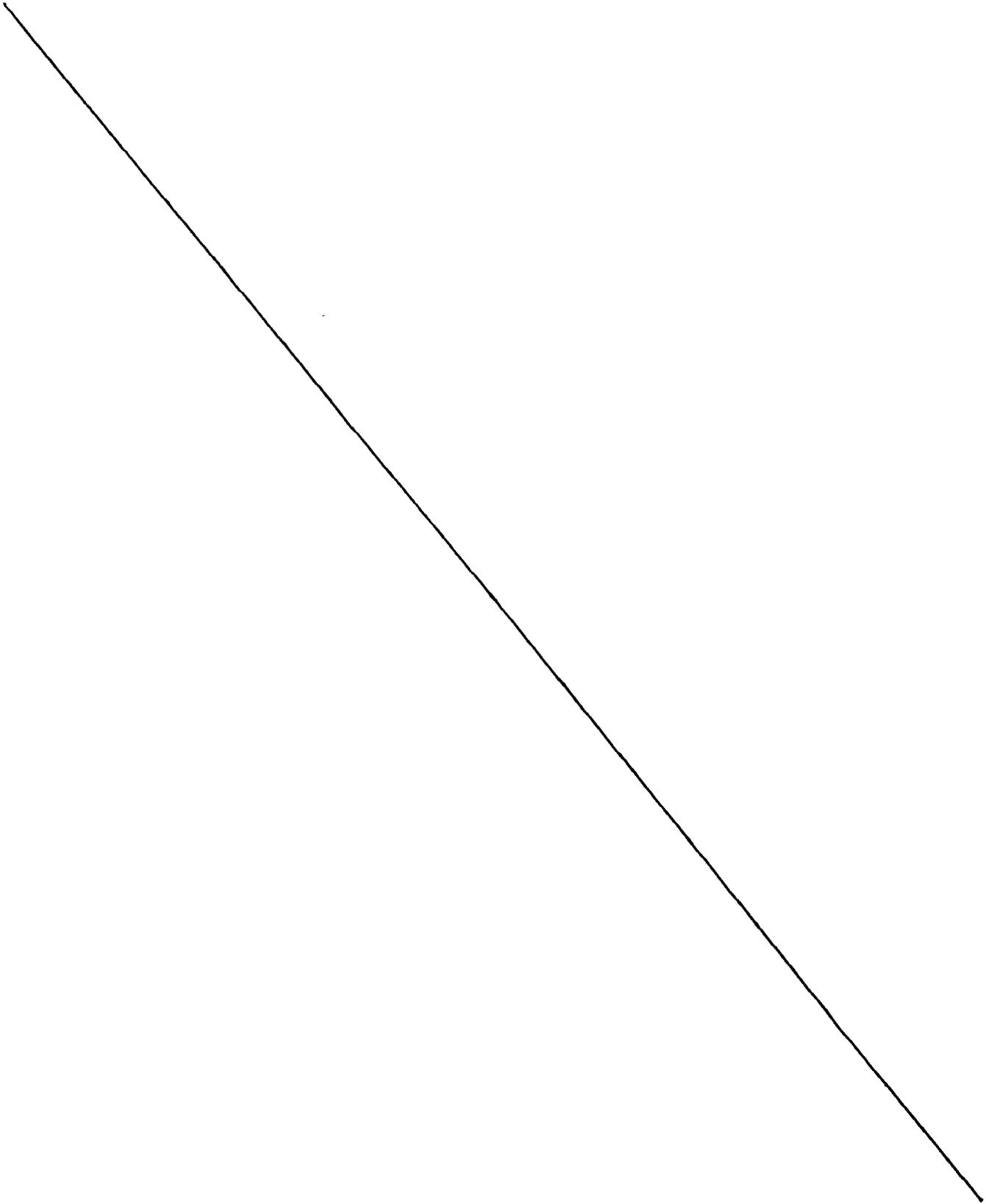
Agenda: On July 20, 2004, the subcommittee will address the following issues: (1) Receive topic updates for ongoing activities pertaining to manufacturing science and quality by design; and (2) discuss and provide comment on a Current Good Manufacturing Practice (cGMP) risk model being developed at FDA. On July 21, 2004, the subcommittee will address the following issues: (1) Discuss and provide comments on a cGMP and quality system approach for the production of investigational new drugs (INDs) and (2) discuss and provide comments on manufacturing science and risk-based questions for new drug application chemistry, manufacturing and controls (NDA CMC) review process.

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 July 13, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on July 20, 2004, and between approximately 11:30 a.m. and 12 noon on July 21, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 13, 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 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: 5/20/04
May 20, 2004.

Peter J. Pitts

Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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