Dated: February 10, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–2210 Filed 2–15–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Date and Time: The meeting will be held on April 18 and 19, 2006, 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: Mimi T. Phan, 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: 301–827–6778, e-mail: *PHANM@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.

Agenda: On April 18, 2006, the subcommittee will: (1) Receive topic updates for ongoing activities pertaining to the International Conference on Harmonisation (ICH) Q8, Q9, Q10, and future ICH quality topics; and (2) discuss and provide comments on modernized Current Good Manufacturing Practice (CGMP) approaches to process validation that encourage continuous improvement over the product life-cycle. On April 19, 2006, the subcommittee will: (1) Discuss and provide comments on the agency's new approaches to Chemistry, Manufacturing, and Control (CMC) guidance development, as illustrated by the comparability protocol guidance; (2) discuss and provide comments on the CMC Pilot Program; and (3) receive an update on the Cooperative Research and Development Agreement (CRADA) with Conformia Software, Inc., to obtain information on factors influencing pharmaceutical development. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2006 and scroll down to the Advisory Committee for Pharmaceutical Science meetings.)

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 April 11, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on April 18, 2006, and between approximately 11:30 a.m. and 12 noon on April 19, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 11, 2006, 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 Mimi Phan 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: February 9, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–2237 Filed 2–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N–1852] (formerly 99N–1852)

Guidance for Industry on Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997.'' This guidance provides recommendations on procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product; timeframes for FDA's review of postmarketing study commitments; and information about postmarketing study commitments that will be available to the public. The guidance is intended to assist applicants in meeting the requirements of section 130 of the Food and Drug Administration Modernization Act of 1997.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800.

Submit written comments on the 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*. See