tobacco and the FDA Modernization Act.

DATES: The meeting will be held on Thursday, May 28, 1998, from 2 p.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Bethesda Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6630. *Registration:* There is no registration fee, however, space is limited. Persons will be registered in the order in which calls are received. Please call Betty Palsgrove at 301–827–6618 to register. Registrations also may be transmitted by FAX to 1–800–344–3332 or 301–443–2446. Please include the name and title of the person attending and the name of the organization.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff. It will also provide an opportunity for informal discussion on these topics of particular interest to health professional organizations.

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: May 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13410 Filed 5–15–98; 2:58 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

First Party Audit Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of industry exchange meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an industry exchange meeting to discuss with the regulated industry a new initiative being considered by the agency. The First Party Audit Program (FPAP) is intended to gather information from selected human use pharmaceutical manufacturers regarding their quality assurance measures. This information would be submitted to FDA by those firms and would substitute, in some measure, for information the agency would otherwise obtain from its direct inspectional activities. The industry exchange meeting is intended to present the broad concepts of this initiative, discuss attendant issues, and obtain feedback from all interested parties as to the merits of proceeding with the project. This meeting is cosponsored by the Center for Drug Evaluation and Research's (CDER's) Office of Compliance and the Office of the Commissioner's Industry Small Business and Community Affairs Staff.

DATES: The industry exchange meeting will be held on June 23, 1998, from 9 a.m. to 4 p.m. Registration is required by June 12, 1998.

ADDRESSES: The industry exchange meeting will be held at the Hyatt Regency Bethesda Hotel, One Bethesda Metro Center, Bethesda, MD.

FOR FURTHER INFORMATION CONTACT: C. Russ Rutledge, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2455.

Those persons interested in attending this meeting should FAX or e-mail their registration to C. Russ Rutledge (FAX 301–594–2202 or e-mail via the Internet at ''rutledgec@cder.fda.gov''), including name of attendee(s), title, affiliation, mailing address, phone number, fax number, and e-mail address. There is no registration fee for this meeting, but advance registration is required. Interested parties are encouraged to register early because space is limited.

SUPPLEMENTARY INFORMATION: FDA relies in large part on information acquired during inspections of manufacturing facilities, conducted by the agency's investigators, to ensure that firms are meeting the minimum levels of product quality assurance for human drug products. Although the agency believes that full inspection by its investigators is the ideal situation, FDA is evaluating alternative methods of acquiring information it would otherwise directly obtain from traditional onsite inspections. One approach the agency is considering is the FPAP. The first party is the manufacturing firm itself. The concept is to limit program participation to those manufacturers FDA recognizes as having both a quality assurance program that is effective and a record of substantial compliance with FDA requirements. Program participation would be strictly voluntary. Firms the agency selects for the program would supply FDA with information from its self-audits apart from FDA onsite inspections. The agency would use this information along with modified inspections to document minimum levels of assurance of manufacturing quality of the pharmaceuticals produced in that site.

FDA is holding this industry exchange meeting to present the core concepts of FPAP, discuss the relevant issues, and afford interested parties the opportunity to pose questions and provide comments. The agency will consider this public input in deciding on whether and how to proceed with the program, initially on a pilot basis.

The agenda and any other relevant information will be available electronically via the Internet at ''http://www.fda.gov/cder/dmpq/fpap.htm'' beginning Monday, May 18, 1998.

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13163 Filed 5–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 regulatory issues.

Date and Time: The meeting will be held on June 23, 1998, 8 a.m. to 5 p.m., and on June 24, 1998, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, (For Federal Express Deliveries—Chapman Bldg., 801 Thompson Ave., rm. 200, Rockville, MD 20857) or FDA Advisory Committee Information Line,