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,

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 June 23 and 24, 1998, the committee will focus on both safety/efficacy and quality topics with a bridging topic (exposure). Specific topics to be discussed include: (1) Nonclinical/nonhuman pharmacology/toxicology research programs to support the drug development and registration process, (2) in vitro drug metabolism to support guidance updating, (3) the revision of the guidance for scale-up and post-approval changes for immediate release drug products, and (4) complex drug substances.

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 June 16, 1998. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. on June 23, 1998, and between approximately 10:15 a.m. and 10:45 a.m. on June 24, 1998. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before June 16, 1998, 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.

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

Dated: May 11, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–13314 Filed 5–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0451]

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 13, 1998 (63 FR 18029). The document announced the availability of a proposed guide entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.'' The document was published with some errors. This document corrects those errors.

DATES: Written comments on the proposed guide by June 29, 1998.

FOR FURTHER INFORMATION CONTACT:

Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916, FAX 202–260–9653, e-mail: jsaltsma@bangate.fda.gov, or

Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–2975, FAX 202–205–4422, e-mail: msmith1@bangate.fda.gov.

In FR Doc. 98–9636, appearing on page 18029 in the **Federal Register** of Monday, April 13, 1998, the following corrections are made:

1. On page 18029, in the third column, in the first complete paragraph, beginning in the second line from the bottom ''WWW (http://www.fda.gov/dockets/dockets.htm)'' is corrected to read ''WWW (http://www.fda.gov/ohrms/dockets/default.htm)''.

2. On page 18030, in the first column, in the last paragraph, beginning in the third line from the bottom ''WWW (http://www.fda.gov/dockets/dockets.htm)'' is corrected to read ''WWW (http://www.fda.gov/ohrms/dockets/default.htm)''.

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13315 Filed 5–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1998.

Name: Advisory Committee on Infant Mortality.

Date and Time: June 29, 1998; 9:00 a.m.—5:00 p.m.; June 30, 1998; 8:30 a.m.—4:00 p.m.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814, (301) 897–9400

The meeting is open to the public.

Agenda: Topics that will be discussed include: Low-Birth Weight; Discrepancies in Infant Mortality; the Healthy Start Program and Evaluation; and Early Postpartum Discharge.

Anyone requiring information regarding the Committee should contact Dr. Peter C. van Dyck, Executive Secretary, Advisory Committee on Infant Mortality, Health Resources and Services Administration, Room 18–31, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–2204.

Persons interested in attending any portion of the meeting or having questions regarding the meeting should contact Ms. Kerry P. Nesseler, Health Resources and Services Administration, Maternal and Child Health Bureau, Telephone (301) 443–2204.

Agenda items are subject to change as priorities dictate.

Jane M. Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 98–13301 Filed 5–18–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Exxon Valdez Oil Spill Public Advisory Group; Meeting

AGENCY: Department of the Interior, Office of the Secretary.

ACTION: Notice of meeting.

SUMMARY: The Department of the Interior, Office of the Secretary is announcing a public meeting of the Exxon Valdez Oil Spill Public Advisory Group.

DATES: June 1–2, 1998, at 10:30 a.m.

ADDRESSES: Fourth floor conference room, 645 ''G'' Street, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Department of the Interior, Office of Environmental Policy and Compliance, 1689 ''C'' Street, Suite 119, Anchorage, Alaska, (907) 271–5011.

SUPPLEMENTARY INFORMATION: The Public Advisory Group was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska*, Civil Action