

Those individuals interested in making formal oral presentations should notify the contact person 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 on or before July 15, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 18, 2011.

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 Bryan Emery or Rosanna Harvey at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: June 28, 2011.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-16574 Filed 6-30-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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 and Clinical Pharmacology.

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 July 26, 2011, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "Public Meetings at the FDA White Oak Campus". Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: ACPS-CP@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 26, 2011, the committee will discuss presentations by the Office of Generic Drugs (OGD) on bioequivalence issues and quality standards relative to narrow therapeutic index (NTI) drug products as a class. In response to feedback during the April 13, 2010, Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP) meeting, the committee will further discuss the definition and list of NTI drugs, as well as proposed bioequivalence standards for these products. The committee will also receive awareness presentations relevant to OGD's ongoing focus on quality and safety of generic drug products. Presentations will outline current activities seeking to better

understand the impact of formulation and quality on the performance of generic drug products and current thinking related to potential regulatory pathways for these issues.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

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 on or before July 19, 2011. Oral presentations from the public will be scheduled between approximately 11 a.m. to 12 noon, and 4:30 p.m. to 5 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before July 12, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 13, 2011.

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public conduct during advisory committee meetings.

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

Dated: June 27, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Food Reporting Comparison Study (FORCS) and Food and Eating Assessment Study (FEAST) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve

the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 15, 2011 (76 FR 21383). One public comment was received on April 15 requesting a copy of the data collection package. The submission was sent to the requestor on April 21. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Food Reporting Comparison Study (FORCS) and Food and Eating Assessment Study (FEAST) (NCI). **Type of Information Collection Request:** Extension. **Need and Use of Information Collection:** The title of this collection was previously, "24-Hour Dietary Recall Method Comparison and the National Cancer Institute (NCI) Observational Feeding Studies." The objective of the two studies is to compare the performance of the newly developed computerized

Automated Self-Administered 24-Hour Recall (ASA24) approach to collecting 24-hour recall (24HR) data with the current standard, the interviewer-administered Automated Multiple Pass Method (AMPM). The ultimate goal is to determine to what extent the new automated instrument can be used instead of the more expensive interviewer-administered instrument in the collection of dietary intake data. **Frequency of Response:** Twice. **Affected Public:** Individuals. **Type of Respondents:** For the FORCS study, approximately 1,200 adult members from three health maintenance organization plans (in Minnesota, California, and Michigan) between ages 20 and 70 years. For the FEAST study, approximately 90 adult residents from the Washington, DC metropolitan area between ages 20 and 70 years. The annual reporting burden is estimated at 866 hours (see table below). This amounts to an estimated 2598 burden hours over the 3-year data collection period with a total cost to the respondents \$54,293. There are no Capital costs, Operating costs, and/or Maintenance costs to report.

Participants and study	Questionnaire	Number of respondents	Frequency of response	Average time per response minutes/hour	Annual hour burden
General Public for FORCS.	Refusal Reasons and Demographics (Attach 4A, Screen 8).	1770	1	5/60 (0.083)	148
	Contact Information (Attach 4A, Screen 5).	400	1	5/60 (0.083)	33
	Screeners (Attach 5)	400	1.00	5/60 (0.083)	33
	AMPM (Attach 1)	400	1.00	30/60 (0.50)	200
	ASA24 (Attach 2)	400	1.00	30/60 (0.50)	200
	Demographics and Health Questionnaire (Attach 6).	360	1.00	10/60 (0.167)	60
	Demographics, Health and Preference Questionnaire (Attach 7).	360	1.00	15/60 (0.25)	90
	Screeners (Attach 8)	33	1.00	5/60 (0.083)	6
General Public for FEAST.	Reminder Telephone Call (Attach 10)	33	1.00	5/60 (0.083)	6
	Eating 3 meals	33	1.00	135/60 (2.25)	151
	Either AMPM or ASA24 (Attach 1 or 2).	33	1.00	30/60 (0.50)	34
	Demographics and Health Questionnaire (Attach 12).	33	1.00	10/60 (0.167)	11
		3485			866

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information

including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding

the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, Office of Regulatory Affairs at OIRA_submission@omb.eop.gov or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans, contact Frances E. Thompson,