changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) not later than December 31 of each year.

The Council consists of 15 physicians, including the Chair. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists, and chiropractors. Members serve for overlapping 4-year terms.

Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Section 1868(a)(3) of the Act provides for payment of expenses and per diem for Council members in the same manner as members of other advisory committees appointed by the Secretary. In addition to making these payments, the Department of Health and Human Services and CMS provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs in a manner to ensure appropriate balance of the Council's membership.

The Council held its first meeting on May 11, 1992. The current members are: Vincent J. Bufalino, M.D., Chairperson; M. Leroy Sprang, M.D.; Karen S. Williams, M.D.; Joseph A. Giaimo, D.O.; Jonathan E. Siff, M.D., MBA; John E. Arradondo, M.D., MPH; Fredrica E. Smith, M.D.; Pamela A. Howard, M.D.; Tye J. Ouzounian, M.D.; Christopher J. Standaert, M.D.; Arthur D. Snow, Jr., M.D.; Gregory J. Przybylski, M.D.; Jeffrey A. Ross, DPM, M.D.; Roger L. Jordan, O.D.; and Janice A. Kirsch, M.D.

II. Meeting Format and Agenda

The meeting will commence with the Council's Executive Director providing a status report, and the CMS responses to the recommendations made by the Council at the August 18, 2008 meeting, as well as prior meeting recommendations. Additionally, an update will be provided on the Physician Regulatory Issues Team. In accordance with the Council charter, we are requesting assistance with the following agenda topics:

- Physician Fee Schedule Final Rule.
- Outpatient Prospective Payment System, (OPPS)/Ambulatory Surgical Center (ASC) Fee Schedule Final Rule.
- Stark Reform.
- Value Based Purchasing-Efficiency Measures.
- CMS–FDA Collaboration.
- Medically Unlikely Edits (MUE) Update.

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to present a 5-minute oral testimony on agenda issues must register with the DFO by the date listed in the **DATES** section of this notice. Testimony is limited to agenda topics only. The number of oral testimonies may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to the DFO for distribution to Council members for review before the meeting by the date listed in the **DATES** section of this notice. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution by the date listed in the **DATES** section of this notice.

III. Meeting Registration and Security Information

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at the number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

Since this meeting will be held in a Federal Government Building, the Hubert H. Humphrey Building, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. To gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license or passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting.

All persons entering the building must pass through a metal detector. In addition, all items brought to the Hubert H. Humphrey Building, whether personal or for the purpose of presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FUTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).)

Dated: October 9, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–24898 Filed 10–23–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0553]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey to Evaluate the Effectiveness of Mississippi Delta Fish Advisories

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary consumer survey of fishing and fish consumption habits in the Mississippi Delta.

DATES: Submit written or electronic comments on the collection of information by December 23, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey to Evaluate the Effectiveness of Mississippi Delta Fish Advisories

The proposed survey will gather information about fishing and fish consumption habits in the Mississippi Delta region, as well as the respondents' awareness and understanding of the Regional Delta Advisory (RDA) issued by the Mississippi Department of Environmental Quality. Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. In June 2005, the Environmental Protection Agency's (EPA) Office of Water and FDA's Center for Food Safety and Applied Nutrition finalized a Memorandum of Understanding (MOU) to enhance collaboration between FDA and EPA regarding environmental contaminants in fish and shellfish and the safety of fish and shellfish for U.S. consumers. The MOU is available at *http://www.epa.gov/waterscience/fish/files/moufdaepa.pdf*.

The proposed study is phase two of a two phase study designed to determine whether existing fish consumption recommendations issued by the state of Mississippi are adequately protecting sport and subsistence consumers of fish harvested from Delta waters. The final report of phase one, entitled ''Recommended Study Design for a Survey to Evaluate the Effectiveness of Mississippi Delta Fish Advisories,'' is available at *http://www.epa.gov/waterscience/fish/technical/ms-delta.html*. Based on the report cited here, FDA is conducting the proposed survey on behalf of EPA to evaluate the effectiveness of the Mississippi Delta Fish Advisories.The proposed survey will collect information on the extent to which Delta sport and subsistence fishermen and their families are aware of the RDA and its recommendations and the extent to which the respondents have changed their fish consumption behaviors as a result of the advisory. The survey will also document specific behavior changes resulting from the RDA, such as increases or decreases in the amount of locally harvested fish consumed, changes in methods of fish preparation, and consumption or avoidance of specific species of fish.

Results of the survey will provide EPA information about fishing and fish consumption habits in the Mississippi Delta region, as well as the respondents' awareness and understanding of the RDA.

The respondents will be selected from four counties in the Mississippi Delta region. Counties were selected to include a mix of rural and non-rural areas and areas with major water resources affected by the advisory. The selected counties are Coahoma, Holmes, Leflore, and Washington. Only the part of Holmes County that is within the advisory area will be included in the survey.

The total sample will include 400 on-the-banks interviews and 600 household interviews of sport and subsistence fishers who harvest noncommercial fish from the Mississippi Delta advisory area, and individuals in the Mississippi Delta area who consume wild-caught fish from the advisory area. FDA estimates that the survey will take approximately 18 minutes to complete, for a total burden of 300 hours (1,000 x 0.3 = 300).

FDA will conduct 6 cognitive interviews and 20 pretests prior to fielding the survey, for a total additional burden of 16 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive Interviews	6	1	6	1	6
Pretest	20	1	20	0.5	10
Survey	1,000	1	1,000	.30	300
Total					316

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on the agency's prior experience with surveys similar to the proposed survey.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket

management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: October 20, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–25472 Filed 10–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Dermatologic and Ophthalmic Drugs Advisory Committee; 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: Dermatologic and Ophthalmic Drugs Advisory Committee.

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 December 5, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Rockville, Plaza Ballrooms, 1750 Rockville Pike, Rockville, MD. The hotel phone number is 301–468–1100.

Contact Person: Yvette Waples, 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: *yvette.waples@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 301–451–2534. 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: The committee will discuss new drug application (NDA) 22–308, besifloxacin ophthalmic solution, Bausch & Lomb, Inc., proposed for the treatment of bacterial conjunctivitis and NDA 22–369, bimatoprost ophthalmic solution, 0.03%, Allergan, Inc., proposed for the treatment of hypotrichosis of the eyelids.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and 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 November 19, 2008. Oral presentations from the public will be scheduled between approximately 10:40 a.m. and 11:10 a.m. and between approximately 3:30 p.m. and 4 p.m. Those desiring to make 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 November 10, 2008. 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 November 12, 2008.

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 John Lauttman at 301–827–7001, 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/oc/advisory/default.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: October 16, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–25470 Filed 10–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Peripheral and Central Nervous System Drugs Advisory Committee; 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: Peripheral and Central Nervous System Drugs Advisory Committee.

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 January 7 and 8, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Rockville, The Ballrooms, 1750 Rockville Pike, Rockville, MD. The hotel telephone number is 301–468–1100.

Contact Person: Diem-Kieu Ngo, 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: 301–827–6776, e-mail: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 301–451–2543. 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