than 18 years who are current participants in any pregnancy registry for a chronic condition; and

(3) Health Care Providers: to include a mix of health care providers (including specialists, obstetrician-gynecologists, and primary care providers) some who have participated in a pregnancy registry and some who have not participated in a pregnancy registry.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60	1	1	1.0	60.0
Total				60.0

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

The study will involve about 60 respondents and take approximately 1 hour each to complete. These estimates are based on the Contractor's extensive experience with mental models research.

Dated: August 18, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20407 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

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 October 14, 2009, from 8 a.m. to 5 p.m.

Location: The Inn and Conference Center, University of Maryland University College (UMUC), Marriott Conference Centers, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301–985–7300.

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 3014512543. 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) 22–250, with the proposed trade name AMAYA (fampridine) 10 milligram (mg) tablets, manufactured by Acorda Therapeutics, Inc. The proposed indication for this new drug product is to improve walking ability in individuals with multiple sclerosis (MS). MS is a neurological disease that may cause a wide variety of possible symptoms, including in some patients difficulty in walking.

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 September 29, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 September 21, 2009. 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 September 22, 2009.

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 Diem-Kieu Ngo 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: August 19, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20380 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Oncologic 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: Oncologic 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 October 5, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301–977–8900.

Contact Person: Nicole Vesely, 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, 301–827–6793, FAX: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. 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 the following topics:

(1) Supplemental biologics license application (sBLA) 103949/5153.0, PEGINTRON (peginterferon alfa-2b) injection, manufactured by Schering Corp. The proposed indication (use) for this product is as an adjuvant (additional) treatment for melanoma, a kind of skin cancer. The primary treatment for melanoma that is metastatic (has spread) to the lymph nodes is surgery to remove both the original cancer and lymph nodes surrounding the cancer. PEGINTRON's proposed use is as a treatment in addition to, or as an ''adjuvant,'' to surgery.

(2) New drug application (NDA) 022–465, proposed trade name VOTRIENT (pazopanib) tablets, manufactured by GlaxoSmithKline. The proposed indication (use) for this product is for the treatment of patients with advanced renal cell carcinoma, a form of kidney cancer.

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 September 21, 2009. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 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 September 11, 2009. 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 September 14, 2009.

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 Nicole Vesely 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: August 19, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20379 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: October 20–21, 2009.

Closed: October 20, 2009, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: October 20, 2009, 8:30 a.m. to 11:55 a.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: October 20, 2009, 11:55 a.m. to 1 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: October 20, 2009, 1 p.m. to 2:30 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: October 20, 2009, 2:30 p.m. to 2:45 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: October 20, 2009, 2:45 p.m. to 3:15 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: October 20, 2009, 3:15 p.m. to 4:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: October 21, 2009, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview