

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 March 4, 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 AnnMarie Williams, 301-796-5966, 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: November 10, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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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 December 16, 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: On December 16, 2009, during the morning session, the committee will discuss supplemental new drug application (sNDA) 021-743/S-016, TARCEVA (erlotinib) tablets, by OSI Pharmaceuticals, Inc. The proposed indication (use) for this product is first-line maintenance, monotherapy (first-choice, single drug) treatment in patients with a form of lung cancer called non-small cell lung cancer (NSCLC) that is either locally advanced (has spread regionally within the lung and/or within chest lymph nodes) or metastatic (has spread beyond the lung), and who have not progressed (including those patients with stable disease) on first-line treatment with platinum-based chemotherapy (a regimen including a platinum drug (cisplatin or carboplatin) plus another chemotherapy drug).

During the afternoon session, the committee will discuss supplemental new drug application (sNDA) 022-059/S-007, TYKERB (lapatinib) tablets, by SmithKline Beecham Ltd. doing business as GlaxoSmithKline. The proposed indication (use) for this product is in combination with an aromatase inhibitor for the treatment of hormone sensitive advanced or metastatic breast 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 [\[www.fda.gov/AdvisoryCommittees/Calendar/default.htm\]\(http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm\). Scroll down to the appropriate advisory committee link.](http://</p>
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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 December 9, 2009. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., and 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 December 1, 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 December 2, 2009.

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Dated: November 10, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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