

- The use of a daily responder analysis for IBS-D as a primary analysis was included.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the clinical evaluation of drugs for the treatment of IBS. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: May 23, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-13143 Filed 5-30-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of March 30, 2012 (77 FR 19293). The amendment is being made to reflect a change in the **DATES** and **ADDRESSES** portion of the

document. The amendment also provides a Web address where the meeting webcast can be accessed. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, 301-796-3805, Avena.Russell@fda.hhs.gov, or please use the 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 30, 2012, FDA announced that a meeting of the Orthopaedic and Rehabilitation Devices Panel would be held on June 27 and 28, 2012. On page 19293, in the first column the **DATES** portion of the document is changed to read as follows:

The meeting will be held on June 27 and 28, 2012, from 7:30 a.m. to 7 p.m. On page 19293, in the first column, the **ADDRESSES** portion of the document is changed to read as follows:

Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

The meeting will be webcast live and free of charge on both days and can be accessed at the following Web address:

On June 27, Day 1

<http://fda.yorkcast.com/webcast/Viewer/?peid=12f84ea095b445d78e9b115f495392731d>

On June 28, Day 2

<http://fda.yorkcast.com/webcast/Viewer/?peid=901726ab91944b158ac705e48664921c1d>

The webcast will be broadcast using Windows Media Player.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: May 24, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012-13157 Filed 5-30-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

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 July 24, 2012, from 8 a.m. to 5 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: Caleb Briggs, 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, email: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 at <http://www.fda.gov/Advisory>

Committees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss supplemental new drug application (sNDA) 022059/014 with the trade name Tykerb (lapatinib) tablets, application submitted by SmithKline Beecham (Cork) Ltd, Ireland d/b/a GlaxoSmithKline. The proposed indication (use) for this product is in combination with trastuzumab for the treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who have received prior trastuzumab therapy(s).

During the afternoon session, the committee will discuss the evaluation of radiographic review in randomized clinical trials using progression-free survival (PFS) as a primary endpoint in non-hematologic malignancies. They will consider the merits of an independent audit of investigator progression assessment in a pre-specified subgroup of patients instead of an independent review of all progression assessments. The expectation is that an independent audit would streamline the conduct of clinical trials, as well as avoid missing data when no additional protocol specified progression assessments are mandated. Hematologic malignancies are excluded from this discussion because other issues (e.g., blood counts, lymph node exams, and other biomarkers) influence the assessment of PFS.

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 10, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 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 June 29, 2012. 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 2, 2012.

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 Caleb Briggs 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: May 24, 2012.

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

[FR Doc. 2012-13156 Filed 5-30-12; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). To request a copy of the clearance requests submitted to

OMB for review, email paperwork@hrsa.gov or call the HRSA Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Rural Health Information Technology Network Development (OMB No. 0915-xxxx)—[New]

The purpose of the Rural Health Information Technology Network Development (RHITND) Program, authorized under the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)) as amended by Section 201, Public Law 107-251, of the Health Care Safety Net Amendments of 2002, is to improve health care and support the adoption of Health Information Technology (HIT) in rural America by providing targeted HIT support to rural health networks. HIT plays a significant role in the advancement of the Department of Health and Human Services' (HHS) priority policies to improve health care delivery. Some of these priorities include: Improving health care quality, safety, efficiency and reducing disparities, engaging patients and families in managing their health, enhancing care coordination, improving population and public health and ensuring adequate privacy and security of health information.

The intent of the RHITND Program is to support the adoption and use of electronic health records (EHR) in coordination with the ongoing HHS activities related to the Health Information Technology for Economic and Clinical Health (HITECH) Act (Pub. L. 111-5). This legislation provides HHS with the authority to establish programs to improve health care quality, safety, and efficiency through the promotion of health information technology, including EHR. For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103-62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for this program. These measures will speak to the Office's progress toward meeting the goals set.