

center directors, the Chief Counsel, the Associate Commissioner of Regulatory Affairs, and the Chief Scientist. The Task Force is charged with submitting a written report to the Commissioner on the Task Force's findings and recommendations.

The Task Force has held two public meetings,<sup>1</sup> launched an online blog (<http://fdatransparencyblog.fda.gov/>), and opened a docket. The online blog and the docket received over 1,500 comments. The blog, which is ongoing, has offered an opportunity for exchange about specific ideas for transparency at the Agency.

The Task Force is proceeding with the Transparency Initiative in three phases:

- Phase I: FDA Basics.
- Phase II: Public Disclosure.
- Phase III: Transparency to

Regulated Industry.

Phase I is intended to provide the public with basic information about FDA and how the Agency does its work. In early January 2010, FDA launched a Web-based resource called *FDA Basics* (<http://www.fda.gov/fdabasics>). The resource now includes (1) 158 questions and answers about FDA and the products that the Agency regulates, (2) 9 short videos that explain various FDA activities, and (3) 14 conversations with FDA officials about the work of their offices. Each month, senior officials from FDA product centers and offices host online sessions about a specific topic and answer questions from the public about that topic. FDA uses the feedback provided by the public to update this resource.

Phase II relates to FDA's proactive disclosure of information the Agency has in its possession, and how to make information about Agency activities and decisionmaking more transparent, useful, and understandable to the public, while appropriately protecting confidential information. On May 19, 2010, FDA released a report that contains 21 draft proposals about expanding the disclosure of information by FDA while maintaining confidentiality for trade secrets and individually identifiable patient information.

The Task Force solicited comment on the content of the proposals, as well as on which draft proposals should be given priority, for 60 days. The Task Force is reviewing the comments received and will recommend specific proposals to the Commissioner for consideration. The Task Force's recommendations will consider

feasibility and priority, considering other Agency priorities that require resources. Not all of these proposals will necessarily be implemented. Some may require changes in law or regulation; some may require a substantial amount of resources.

Phase III is the subject of this document and is described in more detail in section II of this document.

## II. Phase III: Transparency to Regulated Industry

The third phase of the Transparency Initiative addresses ways FDA can become more transparent to regulated industry to foster a more efficient and cost-effective regulatory process.

Regulated industry provides the public with food, drugs, medical devices, cosmetics, and other widely used and important consumer products. FDA's mission is to protect and promote the public health through oversight of these products.

In order to succeed, FDA must clearly communicate standards and expectations to industry. Communicating requirements and expectations to industry in a more accessible manner promotes understanding of, and compliance with, rules set up to protect the supply of food and medical products.

In response to a request for input from FDA on this topic in March 2010 (75 FR 11893, March 12, 2010), regulated companies requested additional transparency about the standards to which their products are held, the process for soliciting guidance from the Agency, and the progress of regulatory efforts at the Agency. In the report, FDA outlines 19 action items and 5 draft proposals to improve transparency to regulated industry.

The Task Force is soliciting comment on the content of the five draft proposals, as well as on which draft proposals should be given priority, for 60 days. After considering public comment on the draft proposals, the Task Force will recommend specific proposals to the Commissioner for consideration. FDA will begin to implement the action items in the report in 2011.

## III. Request for Comments

FDA is interested in receiving comments from the public about the content of the five draft proposals as well as on which draft proposals should be given priority. 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.

It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Identify the draft proposal which your comment addresses by the number assigned to that proposal. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-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 February 8, 2011, 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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Nicole Vesely, 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: 301-847-8532, email: [nicole.vesely@fda.hhs.gov](mailto:nicole.vesely@fda.hhs.gov), or FDA

<sup>1</sup> Transcripts and the webcast from both public meetings are available on the FDA Web site, <http://www.fda.gov/transparency>.

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:* The committee will hear updates on new drug applications (NDAs) and biologics license applications (BLAs) approved under 21 CFR 314.500 and 601.40 (subpart H and subpart E, respectively, accelerated approval regulations) prior to January 1, 2009. These updates will provide information related to the status of phase IV clinical studies and to difficulties associated with completion of phase IV commitments. Phase IV studies are postmarketing studies to confirm clinical benefit of a drug after it receives accelerated approval.

Specifically, the committee will receive updates on the following products: (1) BLA 125084, trade name ERBITUX (cetuximab), application submitted by Imclone Systems Inc., used in combination with the anticancer agent irinotecan and indicated for the treatment of epidermal growth factor receptor (EGFR)-expressing colorectal cancer that has metastasized (spread beyond the colon or rectum) in patients for whom chemotherapy using irinotecan alone is ineffective or less effective; (2) supplemental BLA (sBLA) 125011/24, trade name BEXXAR (tositumomab and Iodine I 131 tositumomab), application submitted by SmithKline Beecham Corp. doing business as (d/b/a) GlaxoSmithKline, indicated for the treatment of patients with varieties of non-Hodgkin's lymphoma known as CD20 antigen-expressing relapsed or refractory, low grade, follicular, or transformed non-Hodgkin's lymphoma, who have not received the drug Rituximab; (3) NDA 21-673, tradename CLOLAR (clofarabine) for intravenous infusion, application submitted by Genzyme Corp., indicated for the treatment of pediatric patients 1 to 21 years old with acute lymphoblastic leukemia (ALL) whose disease has not responded to or has relapsed following treatment with at least two prior chemotherapy regimens; (4) NDA 21-877, tradename ARRANON (nelarabine) Injection, application

submitted by GlaxoSmithKline, indicated for the treatment of patients with types of leukemia or lymphoma known as T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens; (5) BLA 125147, tradename VECTIBIX (panitumumab), application submitted by Amgen Inc., indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens; and (6) sNDA 21-588/025, tradename GLEEVEC (imatinib mesylate) tablets, application submitted by Novartis Pharmaceuticals Corp., indicated for the adjuvant (additional) treatment of adult patients following complete gross resection (removal) of a form of cancer known as Kit (CD117) positive gastrointestinal stromal tumors (GIST).

Based on the updates provided, the committee will have a general discussion centering on possible ways to improve the planning and conduct of trials to confirm clinical benefit (post marketing requirements). The overall goal will be the optimization of the accelerated approval process with a focus on decreasing the amount of time to confirm (or fail to confirm) clinical benefit while continuing to provide early availability of promising oncology products.

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 January 25, 2011. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 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 January 14, 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 January 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 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: January 3, 2011.

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0633]

#### Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled "Determination of System Attributes for the Tracking and Tracing of Prescription