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.

[FR Doc. 2011–32 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

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

Drugs." This public workshop is intended to provide a forum for discussing potential approaches toward a track and trace system and obtaining input from supply chain partners on attributes and standards for the identification, authentication, and tracking and tracing of prescription drug packages, and to further the Agency's goal of protecting public health by securing the drug supply chain against the introduction of counterfeit and other substandard drugs.

DATES: The public workshop will be held on February 15 and 16, 2011, from 9 a.m. to 5 p.m. Submit electronic or written comments on the posted information or on the workshop to the docket by April 16, 2011.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, room 1503, Silver Spring, MD 20993. To register for the public meeting, e-mail your registration information to *drug.trackandtrace@fda.hhs.gov.* See section III of this document for registration details. Submit electronic comments to *http://www.regulations.gov.* Submit written comments 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 the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4830, e-mail: *connie.jung@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since the formation of the first Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multi-layered approach to securing the supply chain and protecting consumers from the threats posed by counterfeit drugs. The ability to track and trace finished drug products in the supply chain plays a significant role in providing transparency and accountability in the drug supply chain. On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. In addition, section 505D of the FD&C Act directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication, and tracking and tracing of prescription drugs.

In March 2010, FDA issued a final guidance for industry which describes the Agency's current recommendation for standardized numerical identification (also known as serialization) for prescription drug packages (Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages, Guidance for Industry—Final Guidance [1]). This guidance is intended to be the first of several steps that FDA may take to implement section 505D of the FD&C Act and further improve the security of the drug supply chain. As FDA continues to work on developing additional standards for securing the drug supply chain, the agency is seeking public input to ensure that we consider information regarding all supply chain participants.

II. Purpose of the Workshop

This public workshop is intended to explore approaches for achieving an effective and feasible track and trace system for finished prescription drug products from the supply chain stakeholder's point of view, including industry and the public, and to obtain views on system attributes and standards that would facilitate identification, authentication, and tracking and tracing of prescription drug packages. We intend to discuss with stakeholders the necessary elements to accomplish effective authentication and identify desirable features of a track and trace system. Participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives.

By February 4, 2011, FDA will post information on our Web site *(http://www.fda.gov/Drugs/DrugSafety/ucm169828.htm)* under "Standards Development for Prescription Drug Supply Chain Security." as follows:

- Workshop agenda,
- Workshop discussion topics.

III. How To Register for the Workshop

To register for the workshop either: (1) E-mail your registration information to *drug.trackandtrace@fda.hhs.gov* or (2) mail your registration information to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**). Registration information should include registrant name, company or organization, address, phone number, and email address. Registration requests should be received by February 1, 2011. Registration is free. Seats are limited. FDA may limit the numbers of participants from each organization based on space limitations. Registrants will receive confirmation upon acceptance for participation in the workshop. Onsite registration on the day of the meeting will be based on space availability on the day of the event starting at 8 a.m. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop on FDA's Web site at: *http://www.fda.gov/Drugs/DrugSafety/ucm169828.htm.* If you need special accommodations due to a disability, please contact Connie Jung (*see* **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

IV. Parking Information

If you are driving to FDA's White Oak Campus, you should proceed to the South East Surface Parking Lot to park your vehicle. Shuttle service is available from the bus shelters in the South East Lot to Building 1. The FDA campus is a Federal facility, therefore all meeting attendees must enter through Building 1 and follow security procedures.

Dated: *January 3, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–72 Filed 1–6–11; 8:45 am]

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[1] *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm.*

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. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995: