will be posted to the docket at *http://www.regulations.gov.*

VI. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. FDA Guidance on Laser Products—Conformance with IEC 60825–1 and IEC 60601–2–22 (Laser Notice No. 50) (June 2007), available at *http://www.fda.gov/downloads/MedicalDevices/.../ucm094366.pdf.*

Dated: December 15, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29725 Filed 12–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0128] (Formerly Docket No. 2007D–0396)

Serious Drug-Induced Liver Injury: The Importance of Getting It Right: How To Measure and Interpret Drug-Induced Liver Injury Information and Make Correct Diagnoses; Public Conference; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled ''Serious Drug-Induced Liver Injury (DILI): The Importance of Getting It Right: How to Measure and Interpret DILI Information and Make Correct Diagnoses.'' This conference will be cosponsored with the Critical Path Institute (C-Path) and the Pharmaceutical Research and Manufacturers of America. The purpose of the public conference is to discuss, debate, and share views among stakeholders in the pharmaceutical industry, academia, health care providers, patient groups, and regulatory bodies on how best to detect and assess the severity, extent, and likelihood of drug causation of liver injury and dysfunction in people using drugs for any medical purpose.

DATES: The public conference will be held on March 18, 2015, from 8 a.m. to 6 p.m. and on March 19, 2015, from 8 a.m. to 4 p.m.

ADDRESSES: The public conference will be held at the College Park Marriott Hotel & Conference Center, 3501 University Blvd., Hyattsville, MD 20783. The hotel's phone number is 301–985–7300.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4478, Silver Spring, MD 20993–0002, 301–796–0518, email: *lana.pauls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA announced the availability of a guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation'' (74 FR 38035, July 30, 2009). This guidance explains that DILI has been the most frequent cause of safety-related drug marketing withdrawals over the past 50 years and that hepatotoxicity has limited the use of many drugs that have been approved and has prevented the approval of others. It discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration and how changes in the results of those laboratory tests over time, along with symptoms and physical findings, may be used to estimate severity of the injury. The guidance suggests some ''stopping rules'' for interrupting drug treatment and the need to obtain sufficient clinical information to assess causation. FDA published a draft of this guidance in 2006, and comments on the draft were taken into consideration when issuing the final guidance in July 2009. FDA is now interested in obtaining stakeholder input on the issues addressed in this guidance, including comments regarding potential revisions to the guidance.

II. Conference Information

The purpose of the 2015 conference is to invite participants to present their data and views, and to hold open discussion.

A. Registration

A registration fee ($600 for industry registrants and $300 for Federal government and academic registrants) will be charged to help defray the cost of renting the meeting space, providing meals and snacks, covering the travel fees incurred by invited academic (but not government or industry) speakers, and other expenses. The registration process will be handled by C-Path, an independent, nonprofit organization established in 2005 with public and private philanthropic support from the southern Arizona community, Science Foundation Arizona, and FDA.

Additional information on the conference, program, and registration procedures may be obtained on the Internet at *http://www.c-path.org* and *http://www.fda.gov* by typing ''liver toxicity'' into the search box. (FDA has verified the C-Path Web site address but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

B. Transcripts

Please be advised that as soon as a transcript is available of the public conference, it can be obtained in either hardcopy or on CD–ROM after submission of a Freedom of Information Act (FOIA) request. Written FOIA requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Material presented at past programs (from 1999 to 2014) may be accessed at *www.aasld.org.* Click on ''Events and Professional Development'' and then scroll down to ''Drug-Induced Liver Injury Conference.''

Dated: December 15, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29720 Filed 12–18–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2137]

Public Meeting on Patient-Focused Drug Development for Breast Cancer; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on patient-focused drug development for breast cancer. Patient-focused drug development is part of FDA's