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]

BILLING CODE 4164–01–P

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

performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of breast cancer on daily life and patient views on treatment approaches.

DATES: The public meeting will be held on April 2, 2015, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by March 23, 2015 (see **SUPPLEMENTARY INFORMATION** for instructions). Submit electronic or written comments to the public docket by June 2, 2015.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *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 brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/Drugs/NewsEvents/ucm421313.htm.*

FOR FURTHER INFORMATION CONTACT: Pegah Mariani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 240–402–4513, FAX: 301–847–8443, *Sayyedeh.Mariani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected breast cancer as the focus of a public meeting under patient-focused drug development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for that condition. Patient-focused drug development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112–144). The full set of performance commitments is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA committed to obtaining the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a document in the **Federal Register** (78 FR 21613) announcing the disease areas for meetings in fiscal years (FYs) 2013–2015, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. By the end of FY 2015, FDA will initiate a second public process for determining the disease areas for FY 2016–2017. More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting Information

A. Purpose and Scope of the Meeting

The purpose of this patient-focused drug development meeting is to obtain input on the symptoms and other impacts of breast cancer that matter most to patients, as well as perspectives on current approaches to treating breast cancer. FDA expects that this information will come directly from patients, caregivers, and patient advocates. Breast cancer is a disease that can occur in both men and women, caused by an uncontrolled growth of cells in breast tissue. Most breast cancers arise from cells lining the ducts or lobules of the breast. The cancer may spread locally to lymph nodes or distantly to various organs (*i.e.,* bone, liver, brain). Treatment for breast cancer differs depending on the extent of disease and may include a combination of surgery, radiation therapy, conventional chemotherapy, hormonal therapy and/or targeted drug therapy. In addition to prescription medicines, complementary and alternative therapies are available to help manage the side effects of breast cancer treatments.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**).

Topic 1: Symptoms and Daily Impacts That Matter Most to Patients

1. For context, how long ago was your diagnosis of breast cancer? Is your cancer currently in only one area or has it spread to other parts of the breast or lymph nodes or outside of the breast?

2. Of all the symptoms that you experience because of your breast cancer, which one to three symptoms have the most significant impact on your daily life? (Examples may include breast pain, swelling, bone pain, and fatigue.)

3. Are there specific activities that are important to you but that you cannot do at all, or as fully as you would like, because of breast cancer? (Examples may include exercise, sexual activity/intimacy, etc.)

Topic 2: Patient Perspectives on Current Approaches To Treating Breast Cancer

1. Are you currently undergoing any cancer treatments to help reduce or control the spread of your breast cancer? Please describe.

1.1 What do you consider to be the most significant downsides of these treatments? (Examples of downsides may include side effects, going to the hospital for treatment, frequent blood tests, etc.)

1.2 How do these downsides affect your daily life?

2. What supportive care treatments, if any, are you taking to help improve or manage the symptoms you experience because of your breast cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as pain medication, acupuncture, massage therapy, and dietary supplements).

2.1 What specific symptoms do your treatments address?

2.2 How well do these treatments manage these symptoms?

2.3 Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?

3. When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life versus improving the symptoms you experience because of your breast cancer?

4. What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your breast cancer? In particular:

4.1 What information on the potential benefits of these treatments factors most into your decision? (Examples of potential benefits from treatments may include shrinking the tumor, delaying the growth of the tumor, prolonging life, etc.)

4.2 How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include nausea, loss of appetite, fatigue, diarrhea, rash.)

4.3 How do you weigh the potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are developing a hole in the stomach or intestine, liver failure, kidney failure, lung inflammation, blood clot, stroke, heart attack, serious infections, etc.)

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit *http://breastcancerpatientfocused.eventbrite.com.* Please register by March 23. 2015. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Pegah Mariani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by March 16, 2015. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Docket Comments: Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by June 2, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: As soon as a transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm421313.htm.*

Dated: December 15, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29721 Filed 12–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2013–0045]

Department of Homeland Security (DHS) Cybersecurity Education and Awareness (CE&A) National Initiative for Cybersecurity Careers and Studies (NICCS) Cybersecurity Scholarships, Internships, Camps, Clubs, and Competitions Collection

AGENCY: Cybersecurity Education & Awareness Office, DHS.

ACTION: 60-day Notice and request for comments; new collection (request for a new OMB Control No.), 1601—NEW

SUMMARY: The Department of Homeland Security, Cybersecurity Education & Awareness Office, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until February 17, 2015. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: You may submit comments, identified by docket number 2013–0045, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Email: dhs.pra@hq.dhs.gov* Please include docket number DHS- 2013–0045 in the subject line of the message.

SUPPLEMENTARY INFORMATION: Title II, Homeland Security Act, 6 U.S.C. 121(d)(1) To access, receive, and analyze law enforcement information, intelligence information and other information from agencies of the Federal Government, State and local government agencies . . . and Private sector entities and to integrate such information in support of the mission responsibilities of the Department. The following authorities also permit DHS to collect information of the type contemplated: Federal Information Security Management Act of 2002 (FISMA), 44 U.S.C. 3546; Homeland Security Presidential Directive (HSPD) 7, ''Critical Infrastructure Identification, Prioritization, and Protection'' (2003); and NSPD–54/HSPD–23, ''Cybersecurity Policy'' (2008). In May 2009, the President ordered a Cyberspace Policy Review to develop a comprehensive approach to secure and defend America's infrastructure. The review built upon the Comprehensive National Cybersecurity Initiative (CNCI).

In response to increased cyber threats across the Nation, the National Initiative for Cybersecurity Education (NICE) expanded from a previous effort, the CNCI Initiative #8. NICE formed in 2010, and is a nationally coordinated effort comprised of over 20 federal departments and agencies, and numerous partners in academia and industry. NICE focuses on cybersecurity awareness, education, training and professional development. NICE seeks to encourage and build cybersecurity awareness and competency across the Nation and to develop an agile, highly skilled cybersecurity workforce.

The National Initiative for Cybersecurity Careers & Studies (NICCS) Portal is a national online resource for cybersecurity awareness, education, talent management, and professional development and training. NICCS Portal is an implementation tool for NICE. Its mission is to provide comprehensive cybersecurity resources to the public.

Any information received from the public in support of the NICCS Portal is completely voluntary. Organizations