(75 FR 58396), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0231. The approval expires on December 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1756 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0357]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 2010 (75 FR 57962), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0466. The approval expires on January 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1755 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0143; (formerly Docket No. FDA–2008–D–0128)]

Drug-Induced Liver Injury: Are We Ready to Look?; 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 "Drug-Induced Liver Injury: Are We Ready to Look?" The public conference will be cosponsored with the American Association for the Study of Liver Diseases (AASLD) and the Pharmaceutical and Research Manufacturers of America to discuss and debate issues regarding drug-induced liver injury (DILI). The purpose of this conference is to consider the effect of the recommendations in the guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation" since its publication in July 2009 and to seek suggestions for future revision.

DATES: The public conference will be held on March 23, 2011, from 8 a.m. to 6 p.m. and March 24, 2011, from 8 a.m. until 3:30 p.m. Submit either electronic or written comments on Agency guidance at any time.

ADDRESSES: The conference will take place at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20993.

Submit written requests for single copies of the 2009 guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 2009 guidance document.

Submit electronic comments on the 2009 guidance and the issues and questions presented at the conference 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.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4307, Silver Spring, MD 20993–0002, 301–796–0518, e-mail: *lana.pauls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA made available a guidance for industry entitled "Drug-Induced Liver Injury: Premarketing Clinical Evaluation" (*see* 74 FR 38035, July 30, 2009). The 2009 guidance explains that DILI has been the most frequent cause of safety-related drug marketing withdrawals for the past 50 years, and that hepatoxicity has limited the use of many drugs that have been approved and prevented the approval of others. It discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration elevations, and how those laboratory tests might change over time, along with symptoms and physical findings, to allow estimation of severity of the injury. It suggests some rules for stopping or interrupting drug treatment, and the need to obtain additional clinical information to estimate the likelihood of the true cause. Public comments on the draft guidance were sought in 2007 and 2008, and those comments were taken into consideration when issuing the final guidance in July 2009.

II. The Public Conference

A. Why are we holding this conference?

The purpose of the 2011 conference is to discuss the most current information and thinking about how drugs cause liver injury and why certain individuals are more susceptible than others, combining views of both basic science and clinical experts, and selecting for specific debate and discussion issues such as:

- Liver injury and dysfunction in patients,
- Liver reaction to injury,
- Biomarkers and predictors of liver injury and dysfunction, and
- Postmarketing DILI.

B. Is there a fee and how do I register for the conference?

A registration fee will be charged to attendees other than invited speakers to help defray the costs of rental of the meeting spaces, meals and snacks provided, and if possible, to cover travel costs incurred by invited academic (but not Government or industry) speakers, and other costs. The fee for the 2-day meeting is $500 for industry registrants and $250 for Federal Government and academic registrants. Registration fees will be waived for invited speakers and moderators.

The registration process will be handled by AASLD, a not-for-profit organization with extensive experience in planning, organizing, and executing educational meetings.

Additional information on the conference, program, and registration procedures is available on the Internet at *http://www.aasld.org* (go to Conferences and Education, Meetings and Conferences), and also at *http://www.fda.gov* by typing into the search box "liver toxicity." (FDA has verified the AASLD Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Transcripts: The presentations and discussions will be transcribed and published on the Internet at *http://www.aasld.org* for public availability after minor editing by the organizers of the meeting (Lana Pauls and John Senior). Please be advised that as soon as a transcript is available, it will also be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the guidance and the issues and questions presented at the conference. 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 notice. Received comments may be seen in the Division of Dockets Management between 9 a.m. Monday through 4 p.m. Friday.

IV. 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: January 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1759 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0046]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this document is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit either an electronic or written request for participation in this program by February 28, 2011. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address(es) of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit, submit either an electronic request to *http://www.regulations.gov* or a written request to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. If you previously responded to earlier requests to participate in this program and you continue to be interested in participating, please renew your request through a submission to the Division of Dockets Management.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Henderson, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, *e-mail: matt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and availability of biological products to patients. To support this primary goal, CBER has initiated various training and development programs, including programs to further enhance performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to enhance: (1) Its understanding of current industry practices and regulatory impacts and needs and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005. Through these annual notices, CBER is requesting those firms that have previously applied and are still interested in participating, to reaffirm their interest. CBER is also requesting new interested parties to apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include the following: (1) Packaging facilities, (2) quality control and pathology/toxicology laboratories, and (3) regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an