considered all of the comments received and revised the guidance where appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on annual reports for PMAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all Center for Device and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov* or from the Center for Biologics Evaluation and Research (CBER) at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*. To receive ''Annual Reports for Approved Premarket Approval Applications (PMA),'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1585 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR 814.82(a)(7) and 814.84(b) have been approved under OMB control number 0910–0231.

Under section 3506(c)(2)(A) of the PRA, FDA provided a 60-day notice concerning the proposed collection of information set forth in the draft guidance (71 FR 62595, October 26, 2006). In response to the notice, FDA received several comments pertaining to the information collection.

Comments noted that for changes previously submitted in a regulatory submission, requiring a rationale for each change is burdensome and duplicative because FDA already has this information. In response to this comment, FDA modified the guidance to request only limited information for changes that were submitted as either a PMA supplement or 30-day notice, including supplement number and the status of the document.

Comments requested clarification of the type of information, data, and level of detail that need to be provided. In response, FDA removed columns from the proposed ''Changes Table'' in the guidance, including columns for validation testing, implementation date, approval date, and risk analysis.

As a result of modifications made to the guidance in response to comments, the guidance no longer imposes an information collection burden additional to that previously approved in OMB control number 0910–0231. FDA is therefore no longer requesting approval of an additional information collection.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is necessary to send only one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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*.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02765 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–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: Who Gets It? Who Doesn't? Why?; 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): Who Gets It? Who Doesn't? Why?'' This conference will be cosponsored with the Critical Path Institute (C-Path) and the Pharmaceutical Research and Manufacturers of America. Its purpose 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 19, 2014, from 8 a.m. to 6 p.m., and March 20, 2014, from 8 a.m. to 4 p.m.

ADDRESSES: The conference will take place 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. 4482, Silver Spring, MD 20993–0002, 301–796–0518, *lana.pauls@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA announced the availability of guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation'' (74 FR 38035; July 30, 2009). This guidance explained that DILI was the most frequent cause of safety-related drug marketing withdrawals for the past 50 years and that hepatotoxicity has limited 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, 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. It 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 2014 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 costs of renting meeting spaces and the meals and snacks provided. The fee will also be used to cover travel costs 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* and 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, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written 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 2013) may be accessed at *www.aasld.org*. Click on ''Education/Training'' and then scroll down to ''Drug Induced Liver Injury 2013 Program.''

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02755 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Clinical Seq. for UDN.

Date: February 28, 2014.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 3rd Floor Conference Room, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lita Proctor, Ph.D., Extramural Research Programs Staff, Program Director, Human Microbiome Project, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20892, 301–496–4550, *proctorlm@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS).

Dated: February 4, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–02687 Filed 2–7–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Center Core Application Review.

Date: March 10, 2014.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, 5635 Fishers Lane, Terrace Level, Rockville, MD.

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov*.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Career Development and Pathways to Independence Grant Applications.

Date: March 10, 2014.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Rockville, Maryland, Terrace Level, 5635 Fisher's Lane, Rockville, MD 20892.

Contact Person: Jeanette M Hosseini, Ph.D., Scientific Review Officer, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301–451–2020, *jeanetteh@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS).

Dated: February 4, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–02688 Filed 2–7–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Implication of CR diet for validation aging related ailments and disorders.

Date: March 3, 2014.

Time: 11:00 a.m. to 2:00 p.m.