''reasonably needed to treat, diagnose, or cure a population of 4,000 individuals in the United States'', and therefore shall be based on the following information in a HDE application: The number of devices reasonably necessary to treat such individuals.

Section 520(m)(6)(A)(iii) of the FD&C Act (*http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/default.htm*) provides that an HDE holder immediately notify the Agency if the number of devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may petition to modify the ADN if additional information arises.

On August 5, 2008, FDA issued a guidance entitled ''Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf*). The guidance was developed and issued prior to the enactment of FDASIA, and certain sections of this guidance may no longer be current as a result of FDASIA. In the **Federal Register** of March 18, 2014 (79 FR 15130), FDA announced the availability of the draft guidance entitled ''Humanitarian Device Exemption: Questions and Answers; Draft Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff'', that when finalized, will represent FDA's current thinking on this topic.

FDA is requesting the extension of OMB approval for the collection of information required under the statutory mandate of sections 515A (21 U.S.C. 360e–1) and 520(m) of the FD&C Act as amended.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/section of FD&C Act (as amended) or FDASIA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act	6	1	6	100	600
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act	3	1	3	50	150
Request for Determination of Eligibility Criteria—613(b) of FDASIA	2	1	2	10	20
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act	5	1	5	100	500
Total					1,370

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's Center for Devices and Radiological Health receives an estimated average of six HDE applications per year. FDA estimates that three of these applications will be indicated for pediatric use. We estimate that we will receive approximately two requests for determination of eligibility criteria per year. FDA estimates that very few or no HDE holders will notify the Agency that the number of devices distributed in the year has exceeded the ADN. FDA estimates that five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease or condition.

Dated: January 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00691 Filed 1–14–16; 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)]

How Should Liver Injury and Dysfunction Caused by Drugs Be Measured, Evaluated, and Acted Upon in Clinical Trials?

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled ''How Should Liver Injury and Dysfunction Caused by Drugs Be Measured, Evaluated, and Acted Upon in Clinical Trials?'' This conference will be cosponsored with the Critical Path Institute (C-Path). The purpose of the conference is to discuss, debate, and share views among stakeholders in academia, patient groups, regulatory bodies, and the health care and pharmaceutical industries on how best to measure, evaluate, and act upon liver injury and dysfunction caused by drugs used during clinical trials.

DATES: This public conference will be held on March 23, 2016, from 8 a.m. to 6 p.m., and on March 24, 2016, from 8 a.m. to 4 p.m.

ADDRESSES: This public conference will be held at the College Park Marriott Hotel & Conference Center, 3501 University Blvd., East 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, *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, *https://www.gpo.gov/fdsys/pkg/FR-2009-07-30/pdf/E9-18135.pdf*). First, this guidance explains that drug-induced liver injury (DILI) has been the most frequent cause

of safety-related drug marketing withdrawals over the past 50 years and that hepatotoxicity has both limited the use of many drugs that have been approved and prevented the approval of others. Second, this guidance discusses methods of detecting DILI by periodic tests of serum enzyme activities and of bilirubin concentration and how changes in the results of these laboratory tests over time, along with symptoms and physical findings, may be used to estimate the severity of the injury. Third, this guidance suggests some ''stopping rules'' for interrupting drug treatment and mentions the need to obtain sufficient clinical information to assess causation. FDA published a draft of this guidance in 2006, and comments on that draft were taken into consideration when issuing the final guidance in July 2009.

II. Conference Information

The purpose of the 2016 conference is to invite participants to present their data and views and to hold an open discussion. The meetings in recent years have been attended by members of industry, regulatory bodies, and academic consultants, and the topics discussed have included several unresolved issues on which consensus was sought.

Registration: A registration fee ($650 for industry registrants and $325 for Federal government and academic registrants) will be charged to help defray the cost of renting the meeting space, providing meals and snacks, and covering the travel fees incurred by invited academic (but not government or industry) speakers, as well as any 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 at *http://www.fda.gov* by typing ''liver toxicity'' into the search box. (FDA has verified the Web site addresses but is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management, 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. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.*

Materials presented at past programs (from 2007 to 2015) (including copies of slides shown, comments made about the slides, and discussions following the slides) may be accessed at *http://www.aasld.org/events-professional-development/drug-induced-liver-injury-2015-program.* (FDA has verified this Web site address but is not responsible for any subsequent changes to it after this document publishes in the **Federal Register**.)

Dated: January 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00690 Filed 1–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Notice for the President's Advisory Council on Faith-Based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the President's Advisory Council on Faith-based and Neighborhood Partnerships announces the following meetings:

Name: President's Advisory Council on Faith-based and Neighborhood Partnerships Council Meetings.

Time and Date: Monday, February 1st, 2016 1:00 p.m.–5:00 p.m. (EST) and Tuesday, February 2nd, 2016 10:00 a.m.–1:00 p.m. (EST).

Place: Meeting will be held at a location to be determined in the White House complex, 1600 Pennsylvania Ave NW., Washington, DC. Space is extremely limited. Photo ID and RSVP by January 25, 2016 are required to attend the event. Please RSVP to Ben O'Dell at *partnerships@hhs.gov*.

The meeting will be available to the public through a conference call line. Register to participate in the conference call on Monday, February 1st at the Web site *https://attendee.gotowebinar.com/register/7321886895235169026.* Register to participate in the conference call on Tuesday, February 2nd at the Web site *https://attendee.gotowebinar.com/register/4788059050490531842*.

Status: Open to the public, limited only by space available. Conference call limited only by lines available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith- based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices.

Contact Person for Additional Information: Please contact Ben O'Dell for any additional information about the President's Advisory Council meeting at *partnerships@hhs.gov.*

Agenda: For February 1, the agenda will begin with an Opening and Welcome from the Chairperson and Executive Director for the President's Advisory Council for Faith-based and Neighborhood Partnership. Then there will be presentation of any Recommendations for deliberation and vote. Lastly, there will be a discussion of subgroup deliberation as well as elements being considered for recommendations. For February 2, there will presentations on work to address poverty and income inequality after a welcome and opening from the Chairperson and Executive Director for the President's Advisory Council.

Public Comment: There will be an opportunity for public comment at the end of the meeting. Comments and questions can be sent in advance to *partnerships@hhs.gov.*

Dated: January 11, 2016.

Ben O'Dell,

Associate Director for Center for Faith-based and Neighborhood Partnerships at U.S. Department of Health and Human Services.

[FR Doc. 2016–00767 Filed 1–14–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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