

Vaccines and Related Biological Products Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Vaccines and Related Biological Products Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective vaccines and related biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. Ex Officio voting members one each from the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health may be included. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) Expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements. If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm129571.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: January 11, 2016.

Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1203]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information to accompany humanitarian device exemption (HDE) applications and the collection of information regarding the annual distribution number (ADN).

DATES: Submit either electronic or written comments on the collection of information by March 15, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2012-N-1203 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Information to Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements”. Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other

applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements—OMB Control Number 0910-0661—Extension

Under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)), FDA is authorized to exempt a humanitarian use device (HUD) from the effectiveness requirements in sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; (3) the device will not expose patients to an unreasonable or significant risk of illness or injury; and (4) the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (*i.e.*, for profit), except in narrow circumstances. Section 613 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), signed into law on July 9, 2012, amended section 520(m) of the FD&C Act. Under section 520(m)(6)(A)(i) of the FD&C Act, as amended by FDASIA, a HUD approved under an HDE is eligible to be sold for profit if the device meets the following criteria: The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or the device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients, or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) of the FD&C Act, as amended by FDASIA, provides that the Secretary of Health and Human Services will assign an ADN for devices that meet the eligibility criteria to be permitted to be sold for profit. The ADN is defined as the number of devices

“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/FederalFoodDrugandCosmeticAct/FDCAAct/FDCAActChapterVDrugsandDevices/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]

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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, lane.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