

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-2011-D-0514 for “Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act.” 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.

Submit written requests for single copies of the guidance to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Nicole Jones, Associate Director Program Operations, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4108, Silver Spring, MD 20993-0002, 301-796-6062.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 522 of the FD&C Act (21 U.S.C. 360l) provides FDA with the authority to require manufacturers to conduct postmarket surveillance of certain class II or class III devices. This guidance is intended to assist manufacturers of devices subject to section 522 postmarket surveillance orders by providing an overview of section 522 of the FD&C Act, information on how to fulfill section 522 obligations, and recommendations on the format, content, and review of postmarket surveillance plan submissions.

FDA issued the draft of this guidance, originally entitled “Draft Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Section 522 Postmarket Surveillance Studies,” on August 16, 2011 (76 FR 50740). The comment period ended on November 14, 2011.

This document supersedes the guidance entitled, “Guidance for Industry and FDA Staff; Postmarket Surveillance under Section 522 of the Federal Food, Drug, and Cosmetic Act,” dated April 27, 2006.

##### 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 current thinking of FDA on postmarket surveillance under section 522 of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it 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 downloading an electronic copy from the Internet. A search capability for all Center for Devices 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>. Persons unable to download an electronic copy of “Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1754 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 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 822 have been approved under 0910-0449.

Dated: May 10, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-11450 Filed 5-13-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 15, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0661. Also include the FDA docket number found in brackets in the heading of this document.

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

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**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 annual distribution number (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/FederalFoodDrugand>

*CosmeticActFDCAct/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.

In the **Federal Register** of January 15, 2016 (81 FR 2220), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received. One comment was outside of the scope of the four information collection-related topics on which the notice solicits public comment. We did not consider the other comment because it was submitted in a foreign language and was not accompanied by an English translation as required in 21 CFR 10.20(c)(2).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| 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         |

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

| 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  |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| 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          |
| <b>Total</b> .....   |                       |                                    |                        |                             | <b>1,370</b> |

<sup>1</sup> 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: May 11, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–11532 Filed 5–13–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Tribal Management Grant Program; Correction**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Indian Health Service published a document in the **Federal Register** on April 7, 2016, for the FY 2016 Tribal Management Grant Program. The notice contained the incorrect Fiscal Year regarding funding availability.

**FOR FURTHER INFORMATION CONTACT:** Michelle Eagle Hawk, Deputy Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop 08E17, Rockville, MD 20857, telephone (301) 443–1104. (This is not a toll-free number.)

**Correction**

In the **Federal Register** of April 7, 2016, in FR Doc. 2016–07950, on page 20396, in the second column, under the heading “II. Award Information, Estimated Funds Available,” the correct first sentence should read as follows:

The total amount of funding identified for the current fiscal year (FY) 2016 is approximately \$2,412,000.

Dated: May 4, 2016.

**Mary Smith,**

*Principal Deputy Director, Indian Health Service.*

[FR Doc. 2016–11545 Filed 5–13–16; 8:45 am]

**BILLING CODE 4165–16–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Heart, Lung, and Blood 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:* Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Review Committee.

*Date:* June 9–10, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications

*Place:* The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

*Contact Person:* Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, [Pintuccig@nhlbi.nih.gov](mailto:Pintuccig@nhlbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 10, 2016.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016–11397 Filed 5–13–16; 8:45 am]

**BILLING CODE 4140–01–P**

**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 would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

*Date:* June 6–7, 2016.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.