



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

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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, PRAStaff@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/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	No. of Respondents	No. 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.

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