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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 oira_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.

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/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.

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[1]

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: May 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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