



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 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@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 (FD&C Act) (21 U.S.C. 360j(m)), as amended by section 3052 of the 21st Century Cures Act (Cures Act) (Pub. L. 114-255), 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 designed to treat or diagnose a disease or condition that affects not more than 8,000 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; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury and 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 a humanitarian device exemption (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. Under section 520(m)(6)(A)(i) of the FD&C Act, 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, provides that the Secretary of Health and Human Services will determine the annual distribution number (ADN) for devices that meet the eligibility criteria to be permitted to be sold for profit. The Cures Act amended the FD&C Act definition of the ADN as the number of devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States.

Section 520(m)(6)(A)(iii) of the FD&C Act provides that an HDE holder immediately notify the Agency if the number of such 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.

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.

In the *Federal Register* of March 12, 2019 (84 FR 8874), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden¹

Activity/Section of FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) and the Cures Act	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	1	1	1	100	100
Exemption from Profit Prohibition Information--520(m)(6)(A)(i) and (ii) of the FD&C Act	1	1	1	50	50
Request for Determination of Eligibility Criteria--613(b) of FDASIA	1	1	1	10	10
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	1	1	1	100	100
Total					360

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

Our estimated burden for the information collection reflects a decrease in the number of responses and corresponding decrease of 1,010 hours in the total burden since our last OMB approval. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: July 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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