4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2025-N-2195]

# Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 collection related to humanitarian use devices (HUDs) and humanitarian device exemption (HDE).

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2025-N-2195 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

*Docket*: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

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, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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.

Medical Devices; Humanitarian Use Devices --21 CFR Part 814

OMB Control Number 0910-0332--Extension

This collection of information implements the humanitarian use devices (HUDs) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)) and part 814, subpart H (21 CFR part 814, subpart H). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of 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 no more than 8,000 individuals

in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of 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.

Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2) of the FD&C Act. The information collected will assist FDA in making determinations on the following: (1) whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

HUDs approved under a 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 520(m)(6)(A)(i) of the FD&C Act, provides that a HUD approved under an HDE is eligible to be sold for profit if the device meets certain 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) provides that the Secretary of Health and Human Services (the Secretary) 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 8,000 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) 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) provides that an HDE holder may petition to modify the ADN if additional information arises.

The FDA issued guidance entitled *"Humanitarian Device Exemption (HDE) Program* (September 2019) (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf) , which addresses commonly asked questions about HDEs and HUDs, including FDA actions on HDE applications, post-approval requirements, and special considerations for devices marketed under the HDE Program. The guidance document reflects changes in the HDE Program resulting from statutory amendments made by the 21st Century Cures Act (Cures Act) and explains the criteria FDA considers to determine if "probable benefit" has been demonstrated as part of the Agency's decision-making process regarding marketing authorization for a HUD. This guidance document also reflects amendments made to the HDE provision of the FD&C Act by the FDA Reauthorization Act of 2017 (FDARA).

Section 402(j)(5)(B) (42 U.S.C. 282(j)(5)(b)) of the Public Health Service Act (PHS Act), requires a certification to accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515,

or 520(m) of the FD&C Act (21 U.S.C. 354, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. Relevant regulations are found in 21 CFR parts 814, subpart H (humanitarian use devices – HUDs), and discussed in FDA's notice of implementation of the certification on December 12, 2007 (72 FR 70599). Certification is made via form FDA 3674, "Certification of Compliance (https://www.fda.gov/media/134964/download) – Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank."

HUDs are subject to the general restriction that no profit may be made on their use. For HUDs labeled for use in certain populations, FDA exempts a certain number of these devices each year from the prohibition on profit. This number is known as the annual distribution number (ADN). The information gathered by this collection enables FDA to set this number. Failure to collect this information would prevent FDA from assigning an ADN.

The information is submitted to FDA as an "eCopy" via FDA's Center for Devices and Radiological Health (CDRH) Customer Collaboration Portal (https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal). Instructions and information regarding eCopy submission are available on FDA's website at https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-medical-device-submissions and in the FDA guidance document, "eCopy Program for Medical Device Submissions" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions).

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

Table 1.—Estimated Annual Reporting Burden[1,2]

| Activity/ 21 CFR Part/ Form | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Humanitarian Use Devices; 21 CFR Part 814 | | | | | |
| Request for HUD designation—814.102 | 23 | 1 | 23 | 40 | 920 |
| Certification of Compliance (form FDA 3674)[2] | 4 | 1 | 4 | .75 (45 minutes) | 3 |
| HDE Application—814.104 | 3 | 1 | 3 | 328 | 984 |
| HDE Amendments and resubmitted HDEs—814.106 | 3 | 3 | 9 | 50 | 450 |
| HDE Supplements—814.108 | 30 | 1 | 30 | 80 | 2,400 |
| Procedures for review of an HDE, including a request for withdrawal—814.116 | 1 | 1 | 1 | 1 | 1 |
| Notification of withdrawal of institutional review board approval—814.124(b) | 1 | 1 | 1 | 2 | 2 |
| Periodic reports—814.126(b)(1) | 36 | 4 | 144 | 120 | 17,280 |
| Total | | | | | 22,040 |
| Information to Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements | | | | | |
| 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 |
| Reporting Total | | | | | 22,400 |

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

[2] Form FDA 3674 is approved under OMB Control No. 0910-0120. This ICR includes burden only for HUD submissions.

Table 2.--Estimated Annual Recordkeeping Burden[1]

| Activity/21 CFR Part | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| Humanitarian Use Devices; 21 CFR Part 814 | | | | | |
| HDE Records—814.126(b)(2) | 81 | 1 | 81 | 2 | 162 |

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

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

| Activity/ 21 CFR Section | No. of Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Average Burden per Disclosure | Total Hours |
|---|---|---|---|---|---|
| Humanitarian Use Devices; 21 CFR Part 814 | | | | | |
| Notification of emergency use--814.124(a) | 22 | 1 | 22 | 1 | 22 |

[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 an overall decrease of 321 hours and a corresponding decrease of 63 responses. The total hour burden for this information collection is estimated to be 22,584 hours. In a nonmaterial/non-substantive change request (83-C), approved 3/24/2023, we consolidated the information collection activity previously approved under OMB control number 0910-0661 into this information collection. This includes information collection associated with the annual distribution number reporting requirements related to pediatric patients and pediatric populations under section 613 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), which amended section 520(m) of the FD&C Act.

Dated: July 31, 2025.

Grace R. Graham

Deputy Commissioner for Policy, Legislation, and International Affairs.

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