



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

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: Submit written comments (including recommendations) 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 submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

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>).

In the Federal Register of August 7, 2025 (90 FR 38151) 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 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 Burden¹

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 Burden¹

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. The consolidation also included FDA 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” (HDE guidance) (July 2010, updated September 2019) (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf>). The guidance does not affect the estimated burden estimates in this extension.

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Acting, Deputy Commissioner for Policy, Legislation, and International Affairs

