United States Food and Drug Administration

Medical Devices; Humanitarian Use Devices

OMB Control No. 0910-0332 EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations. The regulations implement provisions under sections 515A and 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), codified at 21 CFR part 814, subpart H: Humanitarian Use Devices (HUDs). The regulations set forth procedures for obtaining HUD designation of a medical device and are intended "to encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in not more than 8,000 individua ls in the United States per year," (see 21 CFR 814.100). The information collection also includes burden associated with the submission of humanitarian device exemption applications and annual distribution number reporting requirements.

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. 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:

- 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 humanitarian device exemption (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 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) (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf) was updated in September 2019 to provide clarity to industry and FDA staff about the current review practices for the Humanitarian Device Exemption (HDE) Program. This programmatic guidance addresses commonly asked questions about HDEs and Humanitarian Use Devices (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 Federal Food, Drug, and Cosmetic Act (FD&C Act) by the FDA Reauthorization Act of 2017 (FDARA).

Section 402(j)(5)(B) (42 U.S.C. 282(j)) 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 (21 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. The certification is effected by respondents' completion of Form FDA 3674 entitled, "Certification of Compliance – Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank." Relevant regulations are found in 21 CFR parts 312 (investigational new drugs), 314 (applications to market new drug), 601 (biologic license applications), 807 (premarket device notifications), and 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).

Reporting Requirements:

Pediatric Subpopulation and Patient Information--Section 515A(a)(2)

Requires that an HDE application include a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure and the number of affected pediatric patients.

Exemption from Profit Prohibition--Section 520(m)(6)(A)(i) and (ii)

Provides that the HUD meets the eligibility criteria under section 520(m)(6)(A)(i) to be exempt from the profit prohibition on HUDs approved under an HDE, the Secretary will determine the ADN when the Secretary grants the HDE. The ADN shall be based on the number of such devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States.

Request for Determination of Eligibility Criteria—Section 613(b) of FDASIA

A sponsor of a HUD for which an HDE was approved prior to the enactment of FDASIA on July 9, 2012, may seek a determination that their HUD meets the eligibility criteria for exemption from the profit prohibition for an HUD under section 520(m)(6)(A)(i) of the FD&C Act. If the Secretary determines that the HUD meets the eligibility criteria, the Secretary will determine the ADN for the HUD.

ADN Notification--Section 520(m)(6)(A)(iii)

Requires an HDE holder immediately notify the agency if the number of devices distributed during any calendar year exceeds the ADN.

ADN Modification--Section 520(m)(6)(C)

Provides that an HDE holder may petition to modify the ADN if additional information arises.

Therefore, FDA is requesting OMB approval for the collection of information required under the statutory mandate of sections 515A and 520(m) of the FD&C Act as amended, provisions found in 21 CFR part 814, in the HDE guidance, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

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). The information gathered by this collection enables FDA to determine whether an HDE holder is in compliance with the HDE requirements. It also allows us to determine whether to: (1) grant HUD designation of a medical device; (2) exempt a 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 meets requirements set forth in section 520(m) of the FD&C Act; and (3) grant marketing approval(s) for the HUD. Without the information we are unable to make those determinations. Respondents to this information collection are private, for-profit businesses.

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 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.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

The final rule, "Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies to be Allowed in Electronic Format" (84 FR 68334; 12/16/2019) removed requirements to submit multiple paper copies of medical device regulatory pre-submissions and submissions and replace them with one copy in an electronic format.

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).

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

FDA regulations regarding HUDs do not provide for small business exceptions. Because HDE applicants are not subject to user fees and may not have applied for a small business determination (SBD) approval unless they submitted a fee-based application/notification for another program area, it is difficult to determine the number of respondents that are small businesses. However, we assume that approximately 10 percent of respondents are small businesses.

Submission of HDE applications is entirely voluntary. Because a HUD that meets the HDE standard for approval is exempt from the requirement of establishing a reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the FD&C Act, respondents would not need to submit a more burdensome premarket approval application.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.

FDA published a 60-day notice for public comment in the *Federal Register* of August 7, 2025 (90 FR 38151). No Comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts are provided to respondents of the information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a)

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is

collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3514 (CDRH Premarket Review Submission Cover Sheet; see OMB control number 0910-0120) is name, title, phone number, fax number, email address, and address. FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public (see 21 CFR 20), consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The information collection does not include information that is of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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.

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The total hour burden for this information collection is estimated to be 22,584 hours.

To estimate costs to respondents, we assume a wage rate for the labor category "*Lawyers*"* and double this figure to account for benefits and overhead ($87.86 x 2 = $176(rounded)). We then multiplied this wage rate by the estimated annual burden hours to calculate a total annualized cost burden of $3,974,784 ($176 x 22,584).

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics (occupation code 23-1011) May 2024. https://www.bls.gov/oes/current/oes_nat.htm.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	22,584	$176	$3,974,784

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The activities and ongoing support for this information collection, including reviewing and processing Medical Device Reports, involve approximately 27 full time equivalent employees

(FTEs). Based on an internal cost model, we assume a fully-loaded cost of $362,271.92 per position. We therefore calculate an annualized cost to FDA of $9,781,342 (rounded).

15. Explanation for Program Changes or Adjustments

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.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required.

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with the guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.