United States Food and Drug Administration

Medical Devices; Humanitarian Use Devices
OMB Control No. 0910-0332

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 (the FD&C Act or the 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 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.

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.
FDA continues to rely on 2008 guidance, however we issued draft HDA guidance in June 2018.

This 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).

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 amend, provisions found in 21 CFR part 814, in the related guidance referenced above, 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 us 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 that determination. 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.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. A HUD sponsor will be provided with the opportunity to obtain marketing clearance through the HDE application procedures instead of through either the premarket notification procedures or the premarket approval application procedures. A HUD sponsor will also be provided with the opportunity to obtain an ADN through the HDE application procedures. A separate application is not required.

5. Impact on Small Businesses or Other Small Entities

FDA regulations regarding HUDs provide for no small business exceptions. FDA aids small business through agency staff within the agency, and by providing guidance available from our website at www.fda.gov. 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 to another program area, it is difficult to determine the number of respondents that are small businesses. We estimate that approximately 10 percent of respondents are small businesses.

Submission of HDE applications is entirely voluntary. Respondents who believe that it will not be in their business' interest to submit an HDE application will be unlikely to do so. Moreover, the HDE regulation helps small businesses by exempting them from the requirement for full premarket approval applications (PMAs). Furthermore, section 814.104(b)(5) minimizes the burden on all entities by allowing a responsible individua l of the HDE holder's organization to submit an attestation regarding the charges, in lieu of a Certified Public Accountant for which the organization would be compelled to pay.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements. FDA is unable to determine whether a device is eligible for HUD designation without review of the information provided by respondents and required under the FD&C Act (21 U.S.C. 360d and 360e).

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice soliciting public comment of the information collection in the Federal Register of April 7, 2022 (87 FR 20429). We received one comment, however it was not responsive to the four collection of information topics solicited.

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

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII 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) 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.

Under the Freedom of Information Act (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, 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]

Activity/21 CFR Part	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	20	1	20	40	800
HDE Application—814.104	4	1	4	328	1,312
HDE Amendments and resubmitted HDEs—814.106	20	5	100	50	5,000
HDE Supplements—814.108	116	1	116	80	9,280
Notification of withdrawal of an HDE—814.116(e)(3)	2	1	2	1	2
Notification of withdrawal of institutional review board approval—814.124(b)	1	1	1	2	2
Periodic reports —814.126(b)(1)	50	1	50	120	6,000
Total					22,396
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
Overall Total					22,756

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

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)	62	1	62	2	124

[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.

12b. Annualized Cost Burden Estimate

FDA estimates that the total estimated burden cost to industry relating to this information collection will be $2,839,848, which is the total estimated number of burden hours, 22,902, multiplied by an average wage rate of $124 per hour.*

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	22,902	$124	$2,839,848

* The estimated wage rate for a Lawyer is based on The Bureau of Labor Statistics (BLS) hourly wage rate of $62 for a lawyer (https://www.bls.gov/ooh/legal/lawyers.htm, accessed 7-26-22). The hourly wage rate of $124 assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

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

    FDA estimates that a total of 27 full time equivalent (FTE) positions are used for review of submissions. Based on a cost of $263,326 per employee (fully loaded to include benefits and overhead) based on our FY 2020 FDA Budget Request – Executive Summary – All Table , we estimate the cost to the Federal government is $7,109,802.

15. Explanation for Program Changes or Adjustments

    Our estimated burden for the information collection reflects an increase of 360 total burden hours and a corresponding increase of 5 total annual responses. For efficiency of Agency operations, we are consolidating the related information activity and account for burden associated with HDE regulations currently approved in OMB control number 0910-0661. As a result, there is an increase in the total number of burden hours for this information collection.

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

    Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this 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.