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 individuals in the United States per year," (see 21 CFR 814.100).

FDA is therefore requesting OMB approval of the information collection provisions found in 21 CFR part 814, in the related guidance referenced above, and discussed in this supporting statement.

21 CFR 814.102; *Request for HUD Designation – Reporting*

Prior to submitting an HDE application, the applicant shall submit two copies of a request for HUD designation to FDA's Office of Orphan Products Development.

21 CFR 814.104; *HDE Application – Reporting*

After receiving a HUD designation, the applicant shall submit an HDE application to FDA.

We have updated the burden estimate consistent with new provisions in § 814.104(b)(4)(i)) regarding "Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices" (83 FR 7366; February 21, 2018) (approved under OMB control number 0910-0741). Section 814.104 is being amended to address submission of data from clinical investigations in a Humanitarian Device Exemption (HDE). To the extent the applicant includes data from clinical investigations, the applicant will be required to include the information and statements as described in § 814.104(b)(4)(i). Consistent with our estimate in OMB control number 0910-0741, this revision increases our burden estimate for a Humanitarian Device Exemption (HDE) by 8 hours per submission.**21 CFR 814.106**; *HDE Amendments and Resubmitted HDEs – Reporting*

An HDE applicant may amend a pending HDE or HDE supplement to revise existing information or provide additional information.

21 CFR 814.108; *HDE Supplements – Reporting*

After FDA approval of an original HDE, the holder shall submit supplements for review and approval by FDA before making a change affecting the safety or effectiveness of the device

for which the holder has an approved HDE, unless the change is of a type for which FDA has advised that an alternate submission is permitted.

21 CFR 814.116(e)(3); *Notification of withdrawal of an HDE – Reporting*

The applicant submits a written notice to FDA that the HDE has been withdrawn.

21 CFR 814.124(b); *Notification of withdrawal of IRB approval – Reporting*

A holder of an approved HDE shall notify FDA of any withdrawal of approval for the use of a HUD by a reviewing IRB within 5 working days after receipt of the withdrawal of approval.

21 CFR 814.126(b)(1); *Periodic Reports – Reporting*

The holder of an approved HDE shall submit a periodic report to demonstrate continued compliance with the humanitarian device exemption (HDE) requirements.

21 CFR 814.126(b)(2); *HDE Records – Recordkeeping*
An HDE holder shall maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing IRBs, as well as any other information requested by a reviewing IRB or FDA. Such records shall be maintained in accordance with the HDE approval order.

21 CFR 814.124(a); *Notification of Emergency Use – Third-Party Disclosure*

Enables physicians in an emergency situation to administer a HUD prior to obtaining Institutional Review Board (IRB) approval. In such a situation, the physician is required to provide written notification to the IRB within 5 days after emergency use.

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.

3. Use of Improved Information Technology and Burden Reduction

The final rule, "Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies to be Allowed in Electronic Format" (84 FR 68334, December 16, 2019) amended requirements for medical device premarket submissions to remove paper and multiple copies and replace them with requirements for a single submission in electronic

format. Therefore, 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. While related regulations require the submission of information concerning pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; or otherwise exempt respondents from the requirements related to pediatric subpopulations, these collections of information are approved under OMB Control Nos. 0910- 0661 (expires 9/30/22) and 0910-0748 (expires 5/31/20). 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.

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 individual 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 August 13, 2020 (85 FR

49379). We received two comments, however the comments are not relevant to the information collection.

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 with our Privacy Office to ensure appropriate handling of information collected.

This ICR collects personally identifiable information (PII). The PII collected is for business contact purposes only. The PII submitted via Form FDA 3514 (CDRH Premarket Review Submission Cover Sheet) is individual's name, title, work mailing address, work email address, work telephone number and work fax number.

FDA further 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. FDA also minimized the PII to be collected to protect the privacy of the individuals.

Section 814.122(a) states that any record in the HDE file, including all data and information submitted with or incorporated by reference into the HDE, any HDE supplement, any report under § 814.126, any master file, or any other related submission, will be available for public disclosure in accordance with the restrictions and conditions available to PMA files under § 814.9(b) through (h), the public information regulations at 21 CFR part 20, and any other applicable regulation governing confidentiality of information or public disclosure of information. The confidentiality of information is not affected by the amendments.

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)-(b)(9)). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure. Section 520(c) of the FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4).

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

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
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 IRB approval--814.124(b)	1	1	1	2	2
Periodic reports--814.126(b)(1)	50	1	50	120	6,000
Total					22,396

Table 2.—Estimated Annual Recordkeeping Burden

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeping	Total Annual Records	Average Burden per Recordkeeping	Total Hours
HDE Records--814.126(b)(2)	62	1	62	2	124

Table 3.—Estimated Annual Third-Party Disclosure Burden

Activity/21 CFR Section	No. of Recordkeepers	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
HDE Records--814.126(b)(2)	22	1	22	1	22

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, i.e., fiscal years 2017 through 2019. The number of respondents has been adjusted to reflect updated respondent data. This has resulted in an overall increase of 5,803 hours to the total estimated burden. The number of annual reports submitted under Sec. 814.126(b)(1) in table 1 reflects 50 respondents with approved HUD applications. Under Sec. 814.126(b)(2) in table 2, the estimated number of recordkeepers is 62.

12b. Annualized Cost Burden Estimate

FDA estimates that the total estimated burden cost to industry relating to this information collection will be $2,660,664, which is the total estimated number of burden hours, 22,542, multiplied by an average wage rate of $118 per hour.*

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	22,542	$118	$2,659,956

* The estimated wage rate for a Lawyer is based on The Bureau of Labor Statistics (BLS) hourly wage rate of $59 for a lawyer (https://www.bls.gov/ooh/legal/lawyers.htm, accessed 12-18-20). The hourly wage rate of $118 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 22.5 full time equivalent (FTE) positions are used for review of submissions under 21 CFR part 814 and adherence to section 520(m) of the FD&C Act. 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 5,924,835.

15. Explanation for Program Changes or Adjustments

The number of respondents has been adjusted to reflect updated respondent data.

We have also updated the burden estimate consistent with new provisions in §814.104(b)(4)(i)) regarding "Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices" (83 FR 7366; February 21, 2018) (approved under OMB control number 0910-0741). Section 814.104 is being amended to address submission of data from clinical investigations in a Humanitarian Device Exemption (HDE). To the extent the applicant includes data from clinical investigations, the applicant will be required to include the information and statements as described in § 814.104(b)(4)(i). Consistent with our estimate in OMB control number 0910-0741, this revision increases our burden estimate for a Humanitarian Device Exemption (HDE) by 8 hours per submission. These adjustments have resulted in an overall increase of 5,803 hours to the total estimated burden.

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 is not requesting an exemption from displaying the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.