U.S. 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).

The information collection also supports provisions regarding eCopy submissions found in agency guidance. Specifically, section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), requires the submission of eCopies upon the issuance of final guidance. The guidance entitled, "*eCopy Program for Medical Device Submissions; Guidance for Industry and FDA Staff*," provides, among other things, the standards for a valid eCopy under section 745A(b)(2)(A) of the act for different kinds of medical device submissions, including submissions discussed in this information collection. As explained in the guidance, the inclusion of an eCopy is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version.

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.

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

FDA has plans to issue a direct final rule (RIN 0910-AH48) to remove requirements to submit multiple paper copies of medical device regulatory pre-submissions and submissions and replace them with one copy in an electronic format. We are revising the applicable premarket submissions and registration and listing regulations to make an efficient and effective electronic submission program, including those submissions in this information collection. While the amendments would not make any substantive changes to the data elements within the information collection, respondents may realize a monetary savings from administrative expenses associated with the preparation and mailing of paper submissions currently provided for in the regulations.

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 8/31/19) 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. Based on our SBD data, we estimate that approximately 16 percent of respondents are small businesses (3 of 19 respondents).

This information collection will not have a significant economic impact on a substantial number of small entities. While the number of HDE applications FDA will approve is unknown, FDA believes that it will approve approximately 3 HDE applications per year. 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 October 16, 2017 (82 FR 48096). 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

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.

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 Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

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	19	1	19	40	760
HDE Application--814.104	3	1	3	320	960
HDE Amendments and resubmitted HDEs--814.106	6	5	30	50	1,500
HDE Supplements--814.108	110	1	110	80	8,800
Notification of withdrawal of an HDE--814.116(e)(3)	1	1	1	1	1
Notification of withdrawal of IRB approval--814.124(b)	1	1	1	2	2
Periodic reports--814.126(b)(1)	35	1	35	120	4,200
Total					16,223

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)	247	1	247	2	494

Table 3.—Estimated Annual Third-Party Disclosure Burden

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

The number of respondents in the tables are an average based on data from the past 3 years, i.e., fiscal years 2014 through 2016. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 35 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers is 247.

12b. Annualized Cost Burden Estimate

Multiplying the total estimated annual burden hours (16,739) by an average wage rate of $50 per hour, yields an estimate annual cost to respondents of $836,950.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Specialist	16,739	$50	$836,950

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 allocates approximately 22.5 full time employees to the review of submissions under 21 CFR part 814 and adherence to section 520(m) of the FD&C Act. Assuming a cost of $306,800 per employee (fully-loaded to include benefits and overhead) based on our FY 2017 FDA Budget Request – Executive Summary – All Purpose Table, we estimate the cost to the Federal government is $6,903,000.

15. Explanation for Program Changes or Adjustments

The information collection reflects agency adjustments. Specifically, we have updated the number of respondents within the seven individual reporting elements shown in Q12 of this supporting statement based on a review of recent data regarding these submissions. This results in an overall reduction in the number of respondents to the information collection by 17, from 192 to 175, and a corresponding reduction in burden hours by 2,971, from 19,194 to 16,223 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 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.