Medical Devices; Humanitarian Use Devices

0910-0332

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SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the requirements set forth in this information collection. This collection enforces the requirements of 21 CFR Part 814, Subpart H (Attachment A) and the Final Rule published in the November 3, 1998, Federal Register.

The purpose of the regulation is to implement the humanitarian use device (HUD) provision of the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629) and its amended rule (21 CFR 814, subpart H). The HUD provision has been incorporated into section 520(m) (21 U.S.C. 360j(m)) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Under section 520(m) of the act, FDA is authorized to exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device (1) is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using 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. Section 203 of FDAMA made several changes to section 520(m) of the act, and implements the amendments to the HUD provision mandated by FDAMA.

FDA is requesting OMB approval for the collection of information required by the amendments to 21 CFR part 814 promulgated under the statutory mandate of section 520(m) of the act, as amended by FDAMA.

This information collection is not related to the American Recovery and Reinvestment Act of 2009.

Request for HUD Designation (21 CFR 814.102) – Reporting
Prior to submitting an HDE[1] application, the applicant shall submit a request for HUD designation to FDA's Office of Orphan Products Development.

HDE Application (21 CFR 814.104) – Reporting
After receiving a HUD designation, the applicant shall submit an HDE application to FDA.

HDE Amendments and Resubmitted HDEs (21 CFR 814.106) – Reporting
An HDE applicant may amend a pending HDE or HDE supplement to revise existing information or provide additional information.

HDE Supplements (21 CFR 814.108) – 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.

Notification of withdrawal of an HDE (21 CFR 814.116(e)(3)) – Reporting
The applicant must submit a written notice to FDA that the HDE has been withdrawn.

Notification of Emergency Use (21 CFR 814.124(a)) – Third-Party Disclosure
This section allows 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.

Notification of withdrawal of IRB approval (21 CFR 814.124(b)) – 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.

Periodic Reports (21 CFR 814.126(b)(1)) – Reporting
The holder of an approved HDE shall submit a periodic report to demonstrate continued compliance with the humanitarian device exemption (HDE) requirements.

HDE Records (21 CFR 814.126(b)(2)) – 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.

Submission of information concerning pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended

[1] *HDE* means a premarket approval application submitted pursuant to part 814, subpart H, seeking a humanitarian device exemption from the effectiveness requirements of sections 514 and 515 of the act as authorized by section 520(m)(2) of the act.

to treat, diagnose, or cure; and the number of affected pediatric patients is approved under OMB control numbers 0910-0661, expires 5/31/16, and 0910-0748, expires 3/31/17.

2. Purpose and Use of the Information Collection

   The information gathered by this collection enables FDA (Federal Government) to determine whether an HDE holder is in compliance with the HDE requirements. It will also allow FDA 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 act (21 U.S.C. 360d and 360e) provided that the device meets requirements set forth in section 520(m) of the act; and (3) grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making that determination. Respondents to this information collection are private, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

   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), provides statutory authority to require eCopies after issuance of final guidance (See Public Law No: 112-144). FDA's implementing guidance describes how device companies should replace one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. The eCopy requirement does not require or request any information that is not already submitted to the Agency and/or covered under the existing ICR. OMB approved this non-material/nonsubstantive change on December 17, 2012. FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement.

4. Efforts to Identify Duplication and Use of Similar Information

   FDA believes that the information being collected will not duplicate information already available. 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

   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 HDE applicants that are small businesses. Based on our SBD data, we estimate that approximately 14 percent of respondents are small businesses (1 of 7 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 2 HDE applications per year. Moreover, submission of HDE applications is entirely voluntary. Respondents who believe that it will not be in their business's 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 CPA for which the organization would be compelled to pay.

6. Consequences of Collecting the Information Less Frequently

   This information is necessary to FDA to determine whether a device is eligible for HUD designation and thus exempted from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e). It is also necessary to determine whether an HDE holder is in compliance with the HDE requirements (sections 510(m)(3) and (m)(5)) of the act.

   If FDA did not receive information from potential HUD applicants, FDA would have no basis for granting HUD exemptions. The frequency of FDA's receipt of HDE applications will be determined by the frequency with which applicants submit HDE applications (i.e., occasionally). This frequency cannot be reduced without unnecessarily delaying marketing clearance decisions under section 520(m) of the act.

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 for public comment in the FEDERAL REGISTER of 06/10/2014 (79 FR 33197). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   FDA will not provide payment or gifts to sponsors under the HUD provisions.

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	16	1	16	40	640
HDE Application--814.104	7	1	7	320	2,240
HDE Amendments and resubmitted HDEs--814.106	14	5	70	50	3,500
HDE Supplements--814.108	112	1	112	80	8,960
Notification of withdrawal of an HDE--814.116(e)(3)	8	1	8	1	8
Notification of withdrawal of IRB approval--814.124(b)	3	1	3	2	6
Periodic reports--814.126(b)(1)	32	1	32	120	3,840
Total					19,194

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 2011 through 2013. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 32 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 (19,689) by an average wage rate of $50 per hour, yields an estimate annual cost to respondents of $984,450.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Specialist	19,689	$50	$984,450

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 estimates that 22.5 full time equivalent (FTE) positions will be required to fully implement the collection of information and response to applicants and holders required as a result of the requirements of section 520(m) of the act and the implementing regulation. Based on a cost of $283,487 per position (which is the agency's projected average cost of an FTE including their benefits*), the estimated annual Federal cost is $6,378,458.

    *Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

    After a review under the PRA, we have determined that it is more appropriate to categorize the "Notification of emergency use—814.124(a)" information collection as third-party disclosure because respondents (physicians) provide written notification to the IRB, a "third-party," rather than directly to FDA. We have therefore moved the IC to the newly added third-party disclosure burden table above.

    We have updated the number of respondents based on recent data as follows:
    Reporting: formerly 154 respondents, now 192 respondents.
    Recordkeeping: formerly 43 respondents, now 247 respondents.

    These adjustments have resulted in a burden estimate increase of 7,125 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.