SUPPORTING STATEMENT FOR OMB Number 0910-0332
MEDICAL DEVICES; HUMANITARIAN USE DEVICES
21 CFR Part 814 – Subpart H

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.

Section 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.

Section 814.104 – Reporting
After receiving a HUD designation, the applicant shall submit an HDE application to FDA.

Section 814.106 – Reporting
An HDE applicant may amend a pending HDE or HDE supplement to revise existing information or provide additional information.

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[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.

Section 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.

Section 814.116(e)(3) – Reporting
The applicant must submit a written notice to FDA that the HDE has been withdrawn.

Section 814.124(a) – Reporting
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.

Section 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.

Section 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.

Section 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.

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.

3. Use of Improved Information Technology and Burden Reduction

There are no technical or legal obstacles to the collection of this information. Data regarding pediatric populations or pediatric subpopulations are to be included in the original HDE application under 21 CFR 814.104. FDA accepts and encourages the submission of electronic copies from any manufacturer that wishes to submit an electronic copy with a premarket submission. (See CDRH's website at http://www.fda.gov/cdrh/elecsub.html.)

To date, the use of electronic forms of recordkeeping and submissions to FDA remains voluntary.

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

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 6 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. 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

This collection of information is consistent with the guidelines prescribed in 5 CFR 1320.5.

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 September 7, 2011 (76 FR 55394). 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 collected does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden for this information collection as follows:

12a. Annualized Hour Burden Estimate:

Table 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
814.102	17	1	17	40	680
814.104	5	1	5	320	1,600
814.106	5	5	25	50	1,250
814.108	47	1	47	80	3,760
814.116(e)(3)	3	1	3	1	3
814.124(a)	22	1	22	1	22
814.124(b)	12	1	12	2	24
814.126(b)(1)	43	1	43	120	5,160
Total					12,499

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeping	Total Annual Records	Average Burden per Recordkeeping	Total Hours
814.126(b)(2)	43	1	43	2	86

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The number of respondents in tables 1 and 2 are an average from data for the previous 3 years, i.e., fiscal years 2008 to 2010. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 43

respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers is 43.

12b. Annualized Cost Burden Estimate

Multiplying the total reporting and recordkeeping hours (12,585) by an average rate of $50 per hour, yields an estimate annual cost to respondents of $629,250.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Regulatory Affairs Specialist	12,585	$50	$629,250
Total			$629,250

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

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annual 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. These positions are expected to cost the government about $2,668,500 on average, based on the mix of staff expertise required to implement the HUD provisions. The positions range from GS-5 clerical personnel to GS-15 medical officers; and the average cost for each position is $118,600 ($113,600 for personnel costs and benefits and $5,000 of operating funds per year at a total cost of $118,600 for each full time position).

FTEs	Average Cost/FTE	Total Cost
22.5	$118,600	$2,668,500

15. Explanation for Program Changes or Adjustments

The burden represented by this collection of information has increased by 1,441 hours and 109 respondents since the last time OMB approved this information collection. This increase in burden is the result of adjustments of the number of respondents for each section based on data from the previous 3 years (fiscal years 2008 through 2010) and the number of anticipated responses to § 814.108. The new total burden hours for this collection are 12,585.

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.