

JMB

File No.	10/22/99
Date	10/25/99
Certifier	<i>JMB</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2097]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *(insert date 30 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Humanitarian Use Devices—21 CFR Part 814—Subpart H (OMB Control Number 0910-0332)—Extension

This collection implements the humanitarian use device (HUD) provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and part 814 (21 CFR part 814) subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnosis 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 diagnosis 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.

The information collection herein will allow FDA to determine whether to: (1) Grant HUD designation of a medical device, (2) exempt an HUD from the effectiveness requirements in sections 514 and 515 of the act 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 these determinations. Also, this information enables FDA to determine whether the holder of a humanitarian device exemption (HDE) is in compliance with the HDE requirements.

Description of Respondents: Businesses or others for-profit.

In the **Federal Register** of July 19, 1999 (64 FR 38673), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.102	20	1	20	40	800
814.104(b) and (c)	15	1	15	320	4,800
814.106	15	4	60	50	3,000
814.108	12	1	12	80	960
814.116(d)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.126(b)	1	1	1	2	2
814.126(b)(1)	15	1	15	120	1,800
Total					11,368

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.126(b)(2)	15	1	15	2	30
Total					30

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

I. Explanation of Reporting Burden Estimate

Generally, the information requested from respondents represents an accounting of information already in the possession of the applicant.

In the **Federal Register** of June 26, 1996 (61 FR 33232), the agency issued a final rule for HUD's. FDA based its estimates on comments received on the proposed rule, industry contact, and internal FDA benchmark factors (such as the number of premarket approval applications processed). The numbers generated in the current estimate as shown in Tables 1 and 2 of this document and described in the following paragraphs, are based upon those prior estimates, and they have only been modified if actual numbers over the past 3 years have indicated a significantly different trend.

The first HUD rule became effective in fiscal year (FY) 1997, and FDA has only a few years of actual data to compare to original estimated numbers. Although actual numbers are less than the estimated numbers for this information collection, FDA believes that as manufacturers become more familiar with the program, FDA will experience a larger number of submissions under the provisions discussed as follows:

Section 814.102 estimate assumes that 20 sponsors per year will submit a request for HUD designation. It is estimated to require 40 staff hours to complete each HUD designation request.

Section 814.104 estimate assumes that 15 sponsors per year will submit an HDE application after receiving HUD designation. FDA estimates that it will require an average of 320 staff hours to complete each HDE application.

Section 814.110(a) requires that a new indication for use of an HUD approved under this part be submitted as a new HDE application complying with § 814.104. All burden under this section is included under the estimate for § 814.104.

Section 814.106 estimate assumes that 4 times per year FDA will request or the sponsor will submit additional information or resubmit an HDE or HDE supplement for approximately 15 of the submitted HDE applications. FDA estimates that it will require the respondents to take an average of 50 staff hours to complete each amendment or resubmitted application. If FDA refuses to file the HDE application, requests for an informal conference (under § 814.112(b)) will be processed as an HDE amendment. Responses to approvable and not approvable letters (§ 814.116(b), (c), and (d)) will be processed as HDE amendments. A request for an opportunity for an informal hearing, prior to FDA issuing an order withdrawing approval, under § 814.118(d), will be processed as an HDE amendment. Because FDA only tracks amendments, and not the reasons for the amendment, the burden estimates for the sections listed in Tables 1 and 2 of this document are included in the burden estimate for § 814.106.

Section 814.108 estimate assumes that it will receive approximately 12 supplements for the submitted HDE applications. It is estimated that it will take approximately 80 staff hours to complete each supplemental application.

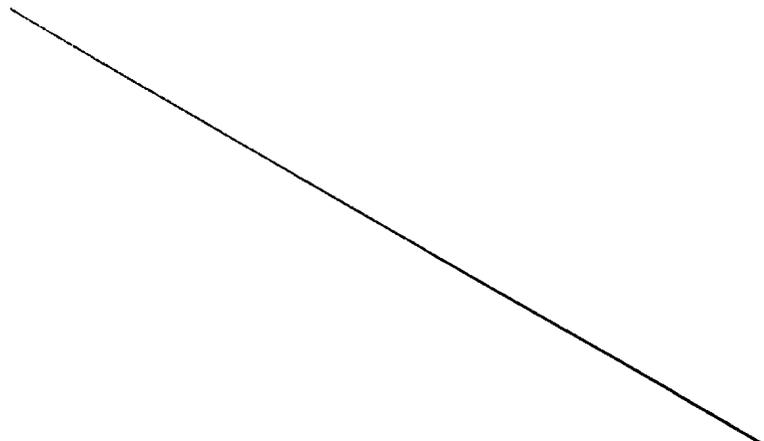
Section 814.116(d)(3) estimate assumes that it will receive approximately one request to withdraw an HDE application per year, based on withdrawals submitted in FY 1997 and FY 1998. FDA estimates it will take no longer than 1 staff hour to complete each written withdrawal notice.

Section 814.124(a) estimate assumes that five physicians will use HUD's in emergency situations before obtaining institute and review board (IRB) approval. FDA estimates that notification under this section will take an average of 1 hour per response.

Section 814.124(b) estimate assumes that one holder of an approved HDE will notify FDA of IRB withdrawal of approval. FDA estimates that it will take an average of 2 staff hours to notify FDA of IRB withdrawal.

Section 814.126(b)(1), following the implementation of the FDA Modernization Act, was amended to incorporate section 520(m)(5) of the act, which provides FDA the authority to require an HDE applicant to demonstrate continued compliance with the HDE requirements, if the agency believes that such a demonstration is necessary to protect the public health or has reason to believe that the criteria for the HDE exemption are no longer met. FDA amended this section to delete the requirement of an annual report and to include instead a periodic reporting requirement that will be established by the approval order for the HDE. This provision permits the agency to obtain sufficient information for it to determine whether there is reason to question the continued exemption of the device from the act's effectiveness requirements.

FDA anticipates that because of this amendment, the 15 HDE holders will remain active and therefore, estimates that 15 periodic reports will be received. FDA also estimates that it will take an average of 120 staff hours to complete a periodic report as a result of this amendment.

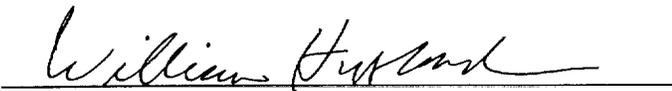
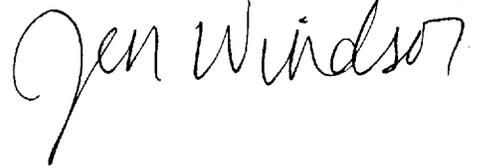


II. Explanation of Recordkeeping Burden Estimate

Section 814.126(b)(2) estimate assumes that 15 HDE holders per year will maintain records of certain required information. It is estimated that it will take an average of 2 staff hours to maintain this information.

Dated: October 18, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



William K. Hubbard
Senior Associate Commissioner
for Policy, Planning and Legislation

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F