4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4951]

Agency Information Collection Activities; Submission for Office of Management and Budget 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 a proposed collection of information 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 (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

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

OMB Control Number 0910-0332--Extension

This collection of information implements the humanitarian use devices (HUDs) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)) and part 814, subpart H (21 CFR part 814, subpart H). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) is designed to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of 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.

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) of the FD&C Act. The information collected will assist FDA in making determinations on the following: (1) whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

In the *Federal Register* of August 13, 2020 (85 FR 49379), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited.

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

Table 1.--Estimated Annual Reporting Burden[1]

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 institutional review board approval--814.124(b)	1	1	1	2	2
Periodic reports--814.126(b)(1)	50	1	50	120	6,000
Total					22,396

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

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

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

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

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

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

The number of respondents in tables 1, 2, and 3 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 § 814.126(b)(1) in table 1 reflects 50 respondents with approved HUD applications. Based on further review, the estimated number of recordkeepers has been adjusted from 65 respondents to

62 respondents in table 2 to reflect the most current data available. Therefore, under § 814.126(b)(2) in table 2, the estimated number of recordkeepers is 62.

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 an 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 an HDE by 8 hours per submission.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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