4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Transfer of a Premarket Notification

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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Transfer of a Premarket Notification." 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.

Transfer of a Premarket Notification

OMB Control Number 0910-New

The draft guidance "Transfer of a Premarket Notification (510(k)) Clearance--Questions and Answers" is intended to provide information on how to notify FDA of the transfer of a 510(k) clearance from one person to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date. The proposed information collection seeks to provide information to notify FDA of the transfer of a premarket notification (510(k)) clearance.

The respondents to this collection of information are 510(k) holders and parties claiming to be 510(k) holders.

In the *Federal Register* of December 22, 2014 (79 FR 76331), FDA published a 60-day notice requesting public comment on the proposed collection of information. While FDA received comments on the draft guidance document, none were related to the information collection.

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Voluntary reporting of transfer of 510(k) clearance on FDA's Unified Registration and Listing System (FURLS) (outside of annual listing reporting requirement)	4,080	1	4,080	0.25	1,020

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
Total					9,152

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

FDA estimates that 78 percent of 510(k)s are listed outside of the annual registration cycle based on numbers in the FURLS database from fiscal year 2009 through fiscal year 2014. Fiscal year 2008 was left out of this cohort as it was the first year that registrants were required to report the 510(k) number on their listings and, therefore, an unusually high number of listings were created. An average of 5,231 510(k)s have been listed each year since 2008. Because listing outside of the annual requirement is voluntary, FDA estimates that annually 78 percent of 510(k)s will continue to be listed outside of the annual requirement. FDA estimates that 4,080 510(k)s may be listed outside of the annual registration cycle. FDA estimates that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

FDA estimates it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. FDA reached this estimate by identifying the number of unique 510(k) device listings entered in FURLS between fiscal years 2009 and 2014 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (6), and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3). The draft guidance identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance. FDA estimates it will take a party approximately 4 hours to locate and submit information to establish the transfer of the 510(k) clearance, resulting in 8,132 burden hours for those 2,033 parties

claiming to be 510(k) holders. FDA reached this estimate based on its expectation of the amount of time it will take a party to locate the information, copy it, and submit a copy to FDA.

The burden estimate does not include the maintenance of records used to document transferring a premarket notification (510(k)) clearance. Based on available information, FDA believes that the maintenance of these records is a usual and customary part of normal business activities. For example, in the ordinary course of business, supporting documents should be kept to verify asset information for calculating the annual depreciation or calculating gain or loss on sale of an asset on a businesses' tax return. Therefore, this recordkeeping requirement creates no additional paperwork burden.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807 (registration and listing) are approved under OMB control number 0910-0625; the collections of information in 21 CFR part 807 subpart E (premarket notification submission) have been approved under OMB control number 0910-0120, and collections of information in 42 CFR 493.17 have been approved under OMB control number 0910-0607.

Dated: March 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-04995 Filed: 3/12/2018 8:45 am; Publication Date: 3/13/2018]