4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0804]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with medical device premarket notification (510(k)).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-0804 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Notification--21 CFR Part 807, Subpart E

OMB Control Number 0910-0120--Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) require a person who intends to market a medical device to submit a 510(k) submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3) (21 CFR 807.92(a)(3)). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), product development protocol, humanitarian device exemption (HDE), request for an evaluation of automatic class III designation (De Novo request), or be reclassified into class I or class II before being marketed (see OMB control numbers 0910-0231, 0910-0332, 0910-0844, and 0910-0138). FDA makes the final decision of whether a device is substantially equivalent or not substantially equivalent.

Section 807.81 states when a 510(k) is required. A 510(k) is required to be submitted by a person who is: (1) introducing a device to the market for the first time; (2) introducing a device into commercial distribution for the first time by a person who is required to register; or (3)

introducing or reintroducing a device that is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device. Section 807.87 lists the information required in each 510(k).

Form FDA 3514, a summary cover sheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, De Novo requests, HDEs, etc.

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) amended section 514 of the FD&C Act (21 U.S.C. 360d). Amended section 514 of the FD&C Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including 510(k) or other requirements. FDA has published and updated regularly the list of recognized standards since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87.

Under § 807.90(a)(3), inquiries regarding a 510(k) submission should be in writing and sent to one of the addresses in § 807.90(a).

Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement).

Section 745A(b) of the FD&C Act, amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52), requires that submissions for devices under section 510(k), among other submission types, be submitted in electronic format specified by FDA. In

addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress,[1] FDA committed to developing "electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process." The Electronic Submission Template and Resource (eSTAR) is such an electronic submission template for 510(k) submissions to facilitate the preparation of submissions in electronic format.

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

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

Activity and 21 CFR Part/ Section	Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response[2]	Total Hours[2]
510(k) submission (807 subpart E)	FDA 3881	3,800	1	3,800	79.25	301,150
Summary cover sheet (807.87)	FDA 3514	1,906	1	1,906	0.5	953
Status request (807.90(a)(3))		1	1	1	0.25	1
510(k) summary (807.92)		2,725	1	2,725	4	10,900
510(k) statement (807.93)		215	1	215	10	2,150
510(k) submission (807 subpart E)—via eSTAR	FDA 4062	100	1	100	40	4,000
eSTAR setup--(one-time burden)		80	1	80	0.08 (5 minutes)	6
Total						319,160

[1].There are no capital costs or operating and maintenance costs associated with this collection of information.
[2].Numbers have been rounded.

Upon review of this information collection, we have made the following changes:

- We have updated the burden estimate consistent with new provisions in § 807.87(j) regarding "Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices" (83 FR 7366; February 21, 2018) (approved under OMB control number

[1] See 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/102699/download.

0910-0741). Section 807.87 was amended to address requirements for 510(k) submissions supported by clinical data. For clinical investigations conducted in the United States, submitters are required to submit a statement as described in § 807.87(j)(1). For clinical investigations conducted outside the United States, submitters are required to submit the information as described in § 807.87(j)(2). Consistent with our estimate in OMB control number 0910-0741, this revision increases our burden estimate for a 510(k) submission by 15 minutes per submission.

- We corrected the burden table to include a line for the "510(k) Summary" under § 807.92. This section was inadvertently removed from the previous version of the information collection request (ICR).

- We are making available Form FDA 3881 "Indications for Use" that respondents include as part of a medical device 510(k). The information provided via the form is already approved under this ICR. The form does not ask for new information and does not bear on the underlying program or on the hour or cost burden associated with the information collection, rather it provides a fillable, 508-compliant format for respondents to use for the "Indications for Use" portion of their 510(k) submission.

- We updated the guidance "Refuse to Accept Policy for 510(k)s" to explicitly recommend providing an Acceptance Checklist in the 510(k) submission. The guidance previously provided the checklist as an example of a tool that FDA staff use when reviewing a 510(k) submission. While it was not explicitly recommended, respondents had used the example and had included it with their 510(k) submission. We believe the checklist can be a helpful tool for both reviewers and 510(k) submitters and have therefore updated the guidance to explicitly recommend inclusion of the checklist in the 510(k) submission. Because most submitters

included the checklist on their own initiative and because it may simplify preparation of the 510(k), we do not believe adding the checklist to this ICR affects the overall burden for a 510(k) submission. Additionally, we have updated the checklist to include combination products, as appropriate. The estimated number of responses as updated with current data in this submission, reflects the inclusion of combination products.

- We revised and reformatted Form FDA 3514, "CDRH Premarket Review Submission Cover Sheet," to improve usability and to be inclusive of most medical device product submission types. Form FDA 3514, a summary cover sheet form, assists respondents in categorizing 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs. The total burden for Form FDA 3514 and for the 510(k) program is estimated in this ICR. The burden for the other medical device programs listed on Form FDA 3514 are approved under the corresponding product submission ICRs as follows: premarket approval applications (OMB control number 0910-0231), investigational device exemptions (OMB control number 0910-0078), humanitarian device exemptions (control number 0910-0332), CLIA waivers (OMB control number 0910-0598), Q-Submissions (OMB control number 0910-0756), De Novo requests (OMB control number 0910-0844), Emergency Use Authorizations (OMB control number 0910-0595), 513(g) requests (OMB control number 0910-0705); and Appeals (OMB control number 0910-0738).

- Certain revisions to Form FDA 3514, as previously described, eliminate the need for Form FDA 3654, "Standards Data Report for 510(k)s." Additionally, the ability for Form FDA 3514 to be expandable for the number of standards cited will increase awareness of actual standards in a submission and how they were used on a single form (compared to including several Form FDA 3654 documents). In the rare occasions where the sponsor elects to not use

Form FDA 3514 for standards, this would not have any effect on the review outcome, with regard to standards, as the form serves as a means to identify what standards are cited, how they are used, and where in the submission they are located.

- We have removed Form FDA 3541, "Status Request." In practice, Form FDA 3541 is rarely used. We have adjusted the burden estimate to reflect this removal. Under § 807.90(a)(3), all inquiries regarding a premarket notification submission should be in writing and sent to one of the addresses listed in § 807.90(a).

- We have added burden estimates for the eSTAR and eSTAR setup (one-time burden). Under section 745A(b) of FD&C Act, amended by section 207 of FDARA (Pub. L. 115-52), and consistent with the MDUFA IV Commitment Letter, FDA has developed the eSTAR (eSTAR, Form FDA 4062) for 510(k) submissions to facilitate the preparation of submissions in electronic format. We expect to receive approximately 100 510(k) submissions via eSTAR per year. We estimate that eSTAR submissions will take approximately 40 hours per submission. Additionally, we've estimated a one-time setup burden of 5 minutes for approximately 80 new eSTAR users annually.

The adjustments and revisions previously mentioned have resulted in a 39,473-hour decrease in the total hour burden estimate since the last OMB approval.

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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