Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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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 Procedures

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: Either electronic or written comments on the collection of information must be submitted by April 24, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 24, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 Procedures.'' 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, 240–402–7500.

- 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, 240–402–7500.

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—Revision

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and implementing regulations in part 807 (21 CFR part 807, subpart E) require a premarket notification submission (510(k)) at least 90 days before 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 determines whether the new device is substantially equivalent to a legally marketed device, as defined in § 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 governs 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 also lists the information required in each premarket notification (510(k)) submission. Each submission should contain the following information:

- Device name;
- Establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission;
- Device class;
- Action taken under section 514 of the FD&C Act (21 U.S.C. 360d) for performance standards; and
- Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.
- A statement indicating that the device is similar to and/or different from other products of a comparable type in commercial distribution, accompanied by data to support the statement.
- For devices that have undergone a significant change or modification, data to show that the manufacturer has considered consequences and effects that a change, modification, or new use might have on the safety and effectiveness of the device.
- A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93 (burden included in §§ 807.92 and 807.93, respectively).
- A financial certification or disclosure statement or both, as required by 21 CFR part 54 (see OMB control number 0910–0396, Financial Disclosure by Clinical Investigators).
- For submissions claiming substantial equivalence to a device which has been classified into class III that was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and for which no final regulation requiring premarket approval has been issued under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)), a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94.
- A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.
- Any additional information regarding the device requested by the Commissioner of Food and Drugs that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution.

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. 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 regularly updated 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.

Section 745A(b) of the FD&C Act (21 U.S.C. 379k–1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (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 Commitment Letter from the Secretary of Health and Human Services to Congress, 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 No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours [1]
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 (30 minutes)	953
Status request (807.90(a)(3)).		1	1	1	0.25 (15 minutes)	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, FDA 4078	100	1	100	40	4,000
eSTAR setup—one-time burden.		80	1	80	0.08 (5 minutes)	6
Request for recognition of a voluntary consensus standard.		9	1	9	1	9
42 CFR part 11, Clinical Trials Registration and Results Information Submission, subparts D and E; and FDA Guidance "Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"						
Certification to accompany 510(k) submissions.	FDA 3674	3,800	1	3,800	0.75 (45 minutes)	2,850
Total						322,019

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

Summary Cover Sheet Form

Form FDA 3514 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.

Status Request

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).

510(k) Summary and 510(k) Statement

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).

Electronic Submission Template and Resource (eSTAR)

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.

Request for Recognition of a Voluntary Consensus Standards

FDA has published and regularly updated 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.

Certification To Accompany PMA Submissions (Section 402(j) of the PHS Act)

The information required under section 402(j)(5)(B) of the PHS Act, recommended in the FDA guidance document ''Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions,'' and associated with the HHS regulations at 42 CFR part 11 (published on September 20, 2016, see 81 FR 64981), is to be submitted with applications currently submitted to FDA under 21 CFR part 814.

Section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act, or submission of a report under section 510(k) of the FD&C Act, such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the FD&C Act have been met. Where available, such certification must include the appropriate National Clinical Trial numbers. We have made Form FDA 3674 available for submitting the certification.

Our estimated burden for the information collection reflects an overall increase of 2,850 hours and a corresponding increase of 3,800 responses. This information collection is being revised to add the estimated burden for ''Certification to accompany 510(k) submissions'' from OMB control number 0910–0616 to this burden estimate.

Dated: February 15, 2023.

Lauren K. Roth,

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