TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
U.S. manufacturers/processors of covered products	450	1	450	0.083	38

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

This information collection gathers the facility name, street address, city, state, and zip code of U.S. manufacturers and processors of covered products, who want to be included on the list sent to China. Because similar information is currently maintained by respondents in conjunction with registration, we believe burden associated with this collection to be minimal. However, as a new information collection, we invite comment specifically in this regard. This is a new information collection. Our estimate is based on our experience with similar information collection.

Dated: April 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08007 Filed 4–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

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

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 May 18, 2020.

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 0910–0120. 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.

Premarket Notification Procedures—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 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 (21 U.S.C. 379k–1(b), 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.

In the **Federal Register** of December 30, 2019 (84 FR 71958) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Upon further evaluation, however, in addition to the revisions discussed in our 60-day notice, we are also revising the information collection to include the draft guidance document entitled ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff.'' The guidance is being issued consistent with our Good Guidance Practice Regulations in 21 CFR 10.115, which provides for comment at any time.

Incorporating burden that may be associated with recommendations discussed in the draft guidance optimizes our operational efficiency with regard to requests to recognize voluntary consensus standards. The draft guidance document is available at *https://www.fda.gov/media/115964/download* and discusses procedures the Center for Devices and Radiological Health (CDRH) will follow when a request for recognition of a voluntary consensus standard is received. The draft guidance outlines justifications for why a standard may be recognized wholly, partly, or not at all, as well as reasons and rationales for withdrawing a standard. The draft guidance also discusses that any interested party may request recognition of a standard and provides respondents with suggested information to include in a request for recognition of a standard.

In the **Federal Register** of September 14, 2018 (83 FR 46740), we published a notice announcing the availability of the draft guidance, including a 60-day notice under the PRA, and invited comment on proposed collection of information. One comment was received stating, information ''required'' for a recommendation for recognition of a standard, a description of how the requirements in the final guidance have been satisfied should also be included along with information about the standard and that a copy of the standard needs to be available to the public at no charge. First, we note that the commenter is incorrect; the draft guidance document states that the information in section IV.B. should be provided when requesting recognition, but it is not required. We believe that requiring a request to include (in addition to the list of recommended items) information regarding how each attribute or element of the voluntary consensus standards development process was met would be unduly burdensome. We remain active in and aware of many national and international voluntary consensus standards bodies and, therefore, are knowledgeable of how these groups address the attributes outlined in OMB Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.'' If we have questions regarding how a specific standard was developed with respect to the voluntary consensus standards development process, we may followup with respondents for additional information on a case-by-case basis (we believe these nonstandardized followup questions designed to clarify responses would be exempt from OMB review and approval under 5 CFR 1320.3(h)(9)).

As indicated in FDA's guidance entitled ''Appropriate Use of Voluntary Consensus Standards in Premarket Submission for Medical Devices'': ''The use of consensus standards is not mandatory for medical device premarket submissions unless the consensus standard has been incorporated by reference into a regulation. A manufacturer may choose to rely on applicable consensus standards or address issues relevant to approval or clearance in another manner.'' Note that the recognition process is separate from creation of regulations that incorporate standards by reference. Consistent with OMB Circular A–119, FDA considers ''reasonable availability'' of a standard when determining whether to incorporate a standard by reference into regulation.

We intend to finalize the guidance and we are seeking OMB approval of the information collection provisions discussed. We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and 21 CFR part; section	Form number	Number of respondents	Number 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
Request for recognition of voluntary consensus standard.		9	1	9	1	9
Total						319,169

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

[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*.

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 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, Section 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, and consistent with the MDUFA IV Commitment Letter,[2] 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.
- We have also added Agency guidance to assist respondents who request recognition of a voluntary consensus standard. The guidance recommends that respondents provide basic contact information to FDA along with details about the specific standard recognition request. Based on previous requests for recognition of standards, we estimate we will receive nine requests annually and assume that each request will take less than 1 hour to prepare.

The adjustments and revisions result in a 39,464-hour decrease in the total hour burden estimate since the last OMB approval.

Dated: April 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08011 Filed 4–15–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Safety Communication Readership Survey; Withdrawal of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a notice that was published in the **Federal Register** of March 6, 2020.

DATES: The notice is withdrawn on April 16, 2020.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White

[2] *https://www.fda.gov/media/102699/download.*