4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1889]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 (PRA).

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 0910-0120. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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 of Devices

OMB Control Number 0910-0120--Revision

This information collection helps support implementation of statutory provisions that govern premarket clearance of devices. 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, subpart E (21 CFR part 807, subpart E), establish premarket notification procedures. Persons who intend to market a medical device, for which a premarket approval application (PMA) is not required, must submit a premarket notification to FDA, unless the device is exempt from 510(k) requirements and does not exceed the limitations of exemptions of the device classification regulations, 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. If a device is determined to be not substantially equivalent to a legally marketed device, it must have an approved 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. The information collection also helps support section 510(l) of the FD&C Act, which provides for exemption from premarket notification.

The following instruments are included in the information collection:

- Form FDA 3514, "CDRH Premarket Review Submission Cover Sheet"
- Form FDA 3881, "Indications for Use"
- Voluntary eSTAR Program Interactive PDF Form and instructional webpage
- Form FDA 4062, "Electronic Submission Template and Resource (eSTAR)" (for non-In Vitro Diagnostic (IVD) 510(k) submissions)
- Form FDA 4078, "Electronic Submission Template and Resource (eSTAR)" (for In Vitro Diagnostic (IVD) 510(k) submissions)

We are revising the information collection to include Form FDA 3674, "Certification of Compliance, Under 42 U.S.C., 282(j)(5)(B), with Requirements of ClinicalTrials.gov." Under applicable authorities, applications 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 Public Health Service Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act, must be accompanied by a certification. Where available, such certification must include the appropriate National Clinical Trial numbers.

The information collection also includes an "Acceptance Checklist." As discussed in the guidance document "Refuse to Accept Policy for 510(k)s" (April 2022), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks, we believe the checklist can be a helpful resource for 510(k) submitters and may simplify preparation of the 510(k). Similarly, the guidance document "Recognition and Withdrawal of Voluntary Consensus Standards" (September 2020), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards, communicates procedures followed by the Center for Devices and Radiological Health (CDRH) when requests for recognition of a voluntary consensus standard for medical products are received. The guidance document outlines principles for recognizing a standard wholly, partly, or not at all, as well as reasons and rationales for withdrawing a standard. Section 514 of the FD&C Act (21 U.S.C. 360d) allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions, including premarket notifications or other requirements. We publish and update the list of recognized standards regularly at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. As instructed in the guidance document, any interested party may submit a request for

recognition of a standard by mail directed to the CDRH Standards Program (i.e., paper copy) or electronically via email.

For efficiency of Agency operations, we are also revising the information to include activities associated with section 520(b) of the FD&C Act, governing custom devices. Regulations in 21 CFR 812.3 define a custom device and implementing regulations in 21 CFR 807.85 provide for exemption from premarket notification. Section 520(b) of the FD&C Act also provides for the issuance of guidance. The guidance document entitled, "Custom Device Exemption" (September 2014), and available for download at https://www.fda.gov/media/89897/download, explains how FDA interprets provisions in section 520(b)(2)(B) of the FD&C Act, describes what information should be submitted in a Custom Device Annual Report ("annual report"), and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption.

Finally, we discuss the guidance document entitled, "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," announced in the *Federal Register* of March 27, 2023 (88 FR 18153), which describes a phased approach intended to help avoid disruption in device supply and help facilitate compliance with applicable legal requirements. The recommendations discussed in the guidance document result in the one-time collection of information intended to ensure an orderly and transparent transition from temporary policies established during the COVID-19 public health emergency to normal operations. Because the information collection recommendations apply to specific medical devices already in distribution, we believe the information discussed is appropriately characterized as nonstandardized followup designed to clarify responses to approved collections of information (i.e., plans for compliance with applicable requirements unique to that distributed device). We therefore believe the activity constitutes the collection of non-identical and/or followup information, as defined under 5 CFR

1320.3. At the same time, we expect some degree of fluctuation in future submissions under part 807, subpart E, as a result of implementation of the medical device transition plan.

In the *Federal Register* of February 21, 2023 (88 FR 10517), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. However, since publication of our 60-day notice, we have adjusted our previous estimate to include burden associated with Form FDA 3674 (submission certification), as well as custom device reporting currently included in OMB control number 0910-0767 and discussed in the *Federal Register* of March 13, 2023 (88 FR 15410).

We estimate the burden of the information collection as follows:

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

Activity and 21 CFR Part/Section	Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR Part 807, Subpart E, Premarket Notification Procedures						
510(k) submission (807 subpart E)	3881	3,800	1	3,800	79.25	301,150
Summary cover sheet (807.87)	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)--using eSTAR format	4062, 4078	100	1	100	40	4,000
Guidance Document Recommendations:						
Submitting information associated with requests for recognition of a voluntary consensus standard		9	1	9	1	9
Annual reporting for custom devices under 520(b) of the FD&C Act		34	1	34	40	1,360
"Form FDA 3674--Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions"						
Certification to accompany 510(k) submissions	3674	3,800	1	3,800	0.75 (45 minutes)	2,850
Electronic Submission Template and Resource (eSTAR)						
eSTAR setup--one-time burden		80	1	80	0.08 (5 minutes)	6
Total				12,670		323,379

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

Both the regulations in part 807, subpart E and the associated guidance documents prescribe specific format and content elements necessary for FDA action on submissions. Based

on recent trends, an estimated 3,800 submissions are expected each year. Our administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that it takes an average of 79.25 hours to prepare a submission. Because the PRA defines a recordkeeping requirement to include a requirement to report those records to the Federal government, we account for burden associated with preparing, transmitting, and responding to followup requests from FDA for supplemental information in our estimate. We expect to receive approximately 100 510(k) submissions via eSTAR per year and estimate that eSTAR submissions will each require 40 hours to complete. In addition, based on a recent review of submissions, we estimate 1,906 summary cover sheets will be received annually. We assume 30 minutes are needed to complete the summary cover sheet. We further estimate that 9 respondents will submit information pertaining to a request for recognition of a voluntary standard and that the activity requires an average of 1 hour. We also account for a one-time setup burden of 5 minutes for an estimated 80 new eSTAR users annually.

As a result of adding burden previously included under OMB control numbers 0910-0616 (submission certification element) and 0910-0767 (custom device exemptions), we have adjusted our burden upward. We have also made nominal adjustments on individual provisions to reflect expected fluctuations in submissions. Cumulatively, these actions result in an overall increase of 3,671 hours and a corresponding increase of 4,210 responses annually.

Dated: June 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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