

# UNITED STATES FOOD & DRUG ADMINISTRATION

## Premarket Notification of Devices

OMB Control No. 0910-0120

### SUPPORTING STATEMENT

*Terms of Clearance:* OMB approved the information collection with the understanding that FDA add the OMB control number, its expiration date, and a burden statement to eSTAR prior to implementation. As reflected in the screenshot/pdf of the webpage used to access eSTAR uploaded with our submission, we have ensured the requisite information is displayed.

#### **Part A: Justification:**

##### 1. Circumstances Making the Collection of Information Necessary

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 (the FD&C Act) and implementing regulations in 21 CFR part 807 subpart E (§§ 807.81 through 807.100), 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 the Food and Drug Administration (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 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. The information collection also helps support implementation of section 510(l), 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** “*Certifications to Accompany Drug, Biological Product, and Medical Device Applications/Submissions.*” 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 PHS 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), 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 Withdraw of Voluntary Consensus Standards,*” (September 2020), 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 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 to: [CDRHStandardsStaff@fda.hhs.gov](mailto:CDRHStandardsStaff@fda.hhs.gov).

For efficiency of agency operations, we are also revising the information to include activities associated with section 520(b) of the FD&C Act (21 U.S.C. 360j(b), governing custom devices. Regulations in 21 CFR 812.3 define a custom device and implementing regulations in 21 CFR part 807.85 provide for exemption from premarket notification. Section 520(b) 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 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 follow-up 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 follow-up information, as defined under 5 CFR 1320.3. At the same time, we expect some degree of fluctuation in future submissions under 21 CFR 807 subpart E, as a result of implementation of the medical device transition plan.

Accordingly, we are requesting OMB approval for the information collection activities included in the applicable regulations, and the guidance documents and agency forms discussed and identified in this supporting statement.

## 2. Purpose and Use of the Information Collection

FDA is mandated under the FD&C Act to make the final decision of whether a device is substantially equivalent or not substantially equivalent to a legally marketed device. The premarket notification review process allows for scientific and/or medical review of devices, subject to 510(k) of the FD&C Act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market.

Additionally, we utilize submission instruments such as forms, the *Acceptance Checklist*, eSTAR, and other web-based process enhancement tools to better focus limited agency resources on reviewing submissions. We also encourage medical device sponsors to use FDA-recognized voluntary consensus standards in submissions, as conformity to relevant standards helps streamline regulatory review, foster quality, and may facilitate a manufacturer's preparation of an Abbreviated 510(k) submission.

Respondents to the information collection are from private sector businesses or other for-profit organizations.

## 3. Use of Improved Information Technology and Burden Reduction

Respondents can make single submissions in an electronic format that includes eCopies, submissions submitted on CD, DVD, or flash drive and mailed to FDA, and eSubmissions, submissions created using an electronic submission template (e.g., "electronic Submission Template and Resource" (eSTAR)). Consistent with our authority in section 745A(b) of the FD&C Act (21 U.S.C. 379k-1(b)), and performance goals found in our Medical Device User Fee Amendments (MDUFA) IV Commitment Letter, we developed eSTAR for use with the Center for Devices and Radiological Health Customer Collaboration Portal. We use eSTAR as a tool to facilitate the preparation of submissions in electronic format (available on FDA's website at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program> and identified as Form FDA 4062 "Electronic Submission Template and Resource (eSTAR)" (for Non-In Vitro Diagnostic submissions) and form FDA 4078 "Electronic Submission Template and Resource (eSTAR)" (for In Vitro Diagnostic submissions)). We believe respondents' use of eSTAR will significantly reduce burden attendant to application submissions by providing a uniform format for requisite elements and by enhancing user interface through the use of modernized technology. We continue to make process improvements and technological

enhancements consistent with our MDUFA V Commitment letter found at <https://www.fda.gov/media/157074/download> (included in OMB control number 0910-0511).

We estimate 99% of the respondents will use electronic means to fulfill the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Upon evaluation of our inventory, we note related information collection activity associated with registration and listing requirements in 21 CFR part 807 subparts A through D. In this information collection we are specifically covering premarket notifications required in 21 CFR part 807 subpart E.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities. Respondents to the information collection submit user fees in conjunction with FDA review of premarket notification of medical devices. Under statutory provisions, small businesses may qualify for reduced fees.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with applicable statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

We published a 60-day notice for public comment in the *Federal Register* of February 21, 2023, (88 FR 10517). In the *Federal Register* of March 13, 2023 (88 FR 15410), we published a notice inviting comment on information collection associated with custom device exemptions specifically. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

*The Privacy Act of 1974*

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3514

(CDRH Premarket Review Cover Sheet) is contact name, work telephone number, work email address, work address, and work fax number. Form FDA 3881 (Indications for Use) is used for this collection, but no PII is collected on this form. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, neither the contractor nor FDA uses name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

#### *The Freedom of Information Act (FOIA)*

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

#### 11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

[BURDEN SUMMARY TABLE NEXT PAGE.](#)

## 12. Estimates of Annualized Burden Hours and Cost

### 12a. Annualized Hour Burden Estimate

Table. 1—Estimated Annual Reporting Burden

Activity and 21 CFR Part/ Section	Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
<b>21 CFR Part 807, Subpart E, PREMARKET NOTIFICATION PROCEDURES</b>						
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)—using eSTAR format	FDA 4062, FDA 4078	100	1	100	40	4,000
<b>Guidance Document Recommendations:</b>						
Request 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
<b>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”</b>						
Certification to accompany 510(k) submissions	FDA 3674	3,800	1	3,800	0.75 (45 minutes)	2,850
<b>Electronic Submission Template and Resource (eSTAR)</b>						
eSTAR setup—one-time burden		80	1	80	0.08 (5 minutes)	6
<b>TOTAL</b>				<b>12,670</b>		<b>323,379</b>

The regulations in 21 CFR 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 reporting those records to the Federal government (5 CFR 1320.3(m)), we account for burden associated with preparing, transmitting, and responding to follow-up requests from FDA for supplemental information in our estimate. We expect to receive approximately 100 510(k) submissions via eSTAR per year. We estimate that eSTAR submissions require 40 hours per submission. Based on a recent review of the summary cover

sheet, we estimate 1,906 summary cover sheets will be received annually. We assume 30 minutes are needed to complete the summary cover sheet. Based on market trends, FDA estimates 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 estimate a one-time setup burden of 5 minutes for approximately 80 new eSTAR users annually.

*12b. Annualized Cost Burden Estimate*

Assuming that activities identified in 12a are performed by labor categories consistent with that of “Lawyer” (occupation code 23-1011) as defined by the Bureau of Labor Statistics (BLS), we use a mean hourly wage rate of \$78.74/hour for a lawyer consistent with 2022 data for our calculations.<sup>1</sup> We factor this figure by two to account for benefits and overhead (\$157.48), multiply the total by the annual burden hours and estimate annual respondent costs to be \$50,711,552 (rounded) [\$157.48 x 322,019 hours].

Respondent Labor Category	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	322,019	\$157.48	\$50,711,552

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate 251 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are allocated to the administration of the information collection. Based on an internal cost model, we assume a fully-loaded cost of \$297,561 per position. We calculate annual Federal costs to be \$74,687,811.

15. Explanation for Program Changes or Adjustments

The information collection reflects program changes and adjustments. As a result of adding burden previously included under control nos. 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.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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<sup>1</sup> [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm), accessed 5/1/23.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB control number, its expiration date, and an explanation of its significance will be displayed with the information collection as required by 5 CFR 1320.5. Consistent with established practice, FDA publishes a *Federal Register* notice announcing OMB approval of the information collection associated with its guidance documents and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to [www.reginfo.gov](http://www.reginfo.gov) to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.