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]

BILLING CODE 4164–01–P

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.*

Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 6, 2020 (85 FR 13171), ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Safety Communication Readership Survey,'' FDA requested comment on the information collection associated with Safety Communication Readership Surveys.

Under the Paperwork Reduction Act of 1995 (the 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.

In the March 6, 2020, **Federal Register** document, FDA proposed to extend the information collection related to the Safety Communication Readership Survey (OMB control number 0910–0341). However, we are withdrawing the notice because, upon further review of the information collection request (ICR), we have determined that it is more appropriate to include the estimated burden expressed in the Safety Communication Readership Survey ICR in the ''generic'' ICR for ''Testing Communications on Medical Devices and Radiation-Emitting Products'' (OMB control number 0910–0678).

Because we intend to submit information collections for safety communication readership surveys under the generic information collection approval, OMB control number 0910–0678, we will discontinue the ICR for OMB control number 0910–0341 and we are withdrawing the March 6, 2020, document requesting comment on the information collection.

Dated: April 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08004 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–2011–N–0424]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Submit either electronic or written comments on the collection of information by June 15, 2020.

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 June 15, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 15, 2020. 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–2011–N–0424 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications.'' 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