GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or *https://www.regulations.gov.*

Dated: February 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03943 Filed 2–26–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0625]

Improving 510(k) Submission Preparation and Review: Voluntary Electronic Submission Template and Resource Pilot Program; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Devices and Radiological Health (CDRH or Center) is announcing its voluntary Electronic Submission Template and Resource (eSTAR) Pilot Program. The eSTAR Pilot Program is voluntary and intends to improve consistency and efficiency in both industry's preparation and FDA's review of premarket notification (510(k)) submissions. During the voluntary eSTAR Pilot Program, pilot participants will have the opportunity to provide input to FDA on eSTAR.

DATES: FDA is seeking participation in the voluntary eSTAR Pilot Program beginning February 27, 2020. See section I.A. for instructions on how to submit a request to participate. The voluntary eSTAR Pilot Program will select up to nine participants who best match the selection criteria. This pilot program will begin February 27, 2020.

ADDRESSES: You may submit comments as follows:

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–2020–N–0625 for ''Voluntary eSTAR Pilot Program.'' Received comments 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 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.

FOR FURTHER INFORMATION CONTACT: Jacqueline Gertz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1655, Silver Spring, MD 20993, 240–402–9677, email: *jacqueline.gertz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the Medical Device User Fee Amendments of 2012 (MDUFA III) Commitment Letter from the Secretary of Health and Human Services to Congress, FDA committed to streamlining review processes by moving beyond paper-based review (Ref. 1). Under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), an electronic copy (eCopy) is required for certain premarket submission types, including 510(k) submissions. FDA provided additional information about the submissions subject to the eCopy requirements in section 745A(b) of the FD&C Act and recommendations about the use of eCopy generally in a guidance initially issued in 2013 (Ref. 2), and subsequently published a final rule in the **Federal Register** of December 16, 2019 (84 FR 68334) amending FDA's regulations, where appropriate, to reflect the requirement of a single submission in electronic format, including the use of eCopy requirements.

In the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter from the Secretary of Health and Human Services to Congress (Ref. 3), 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.'' In addition, section 745A(b) of the FD&C Act, as amended by section 207 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), also requires that presubmissions and submissions for devices, including 510(k) submissions, be submitted in such electronic format as specified in guidance by FDA.

eCopies are an electronic version of a medical device submission created and submitted on a CD, DVD, or flash drive. eSubmissions are submission packages produced by an electronic submission template (*e.g.,* eSubmitter, eSTAR) that contains all the structured and unstructured data of a complete submission. FDA considers both eCopies and eSubmissions to be submissions in electronic format.

As a first step in the transition to submissions solely in electronic format, FDA used the eSubmitter platform to develop an electronic submission template for 510(k) submissions. It is a free tool, and its use is optional. The eSubmitter application includes an electronic submission template that is a collection of questions, text, logic, and prompts that guides a user through preparation of a 510(k) submission. Upon completion, the resulting submission package contains all the structured and unstructured data of a complete 510(k) submission. This platform and submission process is currently being piloted through the ''Quality in 510(k) Review Program Pilot'' (Ref. 4) for the submission of traditional and abbreviated 510(k)s for devices that are reviewed by CDRH and fall under selected product codes.

Based on the experience with the eSubmitter platform, FDA has developed eSTAR, which includes similar benefits as eSubmitter, as well as additional benefits. Similar to eSubmitter, eSTAR includes the following benefits: Automation (*e.g.,* form construction, autofilling); content and structure that is complementary to CDRH internal review templates; integration of multiple resources (*e.g.,* guidances, databases); guided construction for each submission section; automatic verification (*i.e.,* FDA does not intend to conduct a Refuse to Accept (RTA) review (Ref. 5); and it is free to use. In comparison to eSubmitter, eSTAR contains the following additional benefits:

- More intuitive interface
- no special software installation (if the user has Adobe Acrobat or similar software already installed)
- support for images and dynamic pop-up messages
- mobile device and Apple iOS support
- ability to comment when converted to a static PDF
- ability to share (*e.g.,* email) an eSTAR file that is in the process of being constructed
- no necessary packaging process

FDA is announcing and soliciting participation from 510(k) submitters for the voluntary eSTAR Pilot Program. Data collected through the pilot program will help inform FDA on how to improve eSTAR.

A. Voluntary eSTAR Pilot Program Participation

FDA seeks participation in the voluntary eSTAR Pilot Program beginning February 27, 2020. The voluntary eSTAR Pilot Program will select up to nine participants who provide a holistic representation of the medical device industry and meet the selection criteria.

Companies that may be eligible to participate in this voluntary eSTAR Pilot Program are limited to those firms following the procedures set out in section I.B and that also meet all the selection qualities that follow:

1. Intent to submit a traditional, special, or abbreviated 510(k) for a medical device (not a combination product) using eSTAR within 3 months of acceptance to the voluntary eSTAR Pilot Program;

2. willing to provide feedback on eSTAR as outlined in section I.C. of this document; and

3. intent to submit at least one 510(k) for a device that contacts body tissue and includes software.

At its discretion, FDA may withdraw a manufacturer from the voluntary eSTAR Pilot Program for not carrying out any of the commitments mentioned previously.

B. Procedure

To be considered for the voluntary eSTAR Pilot Program, a company should submit a statement of interest for participation to *esubpilot@fda.hhs.gov.* The statement of interest should include agreement to the selection qualities listed in section I.A. of this document, as well as a description of the device in enough detail to allow verification that it is not a combination product, and that it is a software enabled tissue contacting device.

The following captures the proposed process for the voluntary eSTAR Pilot Program:

1. FDA will collect statements of interest for participation in the pilot program beginning February 27, 2020.

The statement of interest should include:

- Agreement to the selection qualities listed in section I.A of this document
- the size of the company by specifying the number of personnel and the amount of revenue per year
- the device(s) that is/are likely to be submitted during the pilot program using eSTAR

2. FDA will select no more than nine participants, who best meet the selection criteria and who reflect the broad spectrum of device manufacturers, including companies that develop a range of products. Enrollment in the pilot program will be ongoing throughout the duration of the program. FDA will apply lessons learned from the initial participants in the pilot program to refine the eSTAR tool with participants.

3. FDA intends to notify the manufacturer via email if the manufacturer is enrolled as a participant in the voluntary eSTAR Pilot Program.

4. The enrolled manufacturer should download eSTAR from the following website: *https://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots. Note:* eSTAR should not be submitted to FDA unless the sponsor is a pilot participant.

5. Directions for preparing and submitting an eSTAR to FDA are in the final section of the eSTAR pdf. We recommend that you use Adobe Acrobat with eSTAR.

6. If eligible and enrolled as a participant, the manufacturer should submit a 510(k) submission prepared and verified using eSTAR within the timeframe identified in the selection criteria in section I.A. of this document.

7. Once the eSTAR-prepared 510(k) is received by FDA, FDA does not intend to conduct the RTA process. The remainder of the procedure will be conducted according to the FDA guidance ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications'' (Ref. 6) and the procedures identified in 21 CFR part 807, subpart E. However, if the contents of any attachment or text field are irrelevant to the purpose of the attachment or text field (*e.g.,* the Device Description attachment does not contain any descriptive information about the device) we may put your submission on hold, and request this particular information only, before beginning a comprehensive review.

8. Following completion of the review of 510(k)s in the voluntary eSTAR Pilot Program, participating manufacturers will have the opportunity to provide individual feedback on the voluntary

eSTAR Pilot Program through the procedures outlined on the voluntary eSTAR Pilot Program website. Non-pilot participants are welcome to submit feedback to the Docket (see **ADDRESSES**).

During the voluntary eSTAR Pilot Program, CDRH staff intends to be available to answer questions or concerns that may arise.

C. Targeted Questions

FDA requests responses to the following questions about eSTAR from pilot program participants and stakeholders outside the pilot who want to submit comments to the docket.

(1) Is eSTAR able to integrate into your organization's business process?

(2) Are you able to open eSTAR, and are you able to add values to the structured data fields, as well as add attachments? Once entered and added, are the data retained after closing and reopening eSTAR?

(3) If you use Assistive Technology, are you able to navigate through and complete eSTAR?

(4) If eSTAR is not intuitive to use, why?

(5) Is the organization and content in eSTAR as expected, or do you have suggestions for improvement?

(6) Is eSTAR able to accommodate PDF attachments that are of the size you typically would provide in a submission?

(7) If all the required questions (indicated by red or green indicators) are provided values, and all the required attachments are added, does eSTAR properly indicate it is complete on the first page, and are all the sections listed in the ''Completed'' column in the final section?

(8) Do you have any suggestions to improve the effectiveness of eSTAR in its purpose, or suggestions to improve the usability?

II. Paperwork Reduction Act of 1995

This notice refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120.

III. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. MDUFA III Commitment Letter, available at: *https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*
2. FDA Guidance for Industry and FDA Staff ''eCopy Program for Medical Device Submissions,'' dated October 10, 2013. This document was superseded by the guidance of the same title dated December 16, 2019, available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.*
3. MDUFA IV Commitment Letter, available at: *https://www.fda.gov/media/102699/download.*
4. Quality in 510(k) Review Program Pilot, available at: *https://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots#quik.*
5. FDA Guidance for Industry and FDA Staff ''Refuse to Accept Policy for 510(k)s,'' dated September 13, 2019, available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.*
6. FDA Guidance for Industry and FDA Staff ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],'' dated July 28, 2014, available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.*

Dated: February 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on January 1, 2020, through January 31, 2020. This list provides the name of petitioner, city and state of vaccination