4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4301]

Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA, the Agency, or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Software Precertification Pilot Program. The program aims to evaluate a new approach toward software products, including a precertification program for the assessment of companies that perform high-quality software design and testing. This voluntary pilot program is part of FDA's ongoing efforts to develop pragmatic approaches to balance benefits and risks of digital health products. FDA intends to develop a precertification program that could replace the need for a premarket submission in some cases and allow for decreased submission content and/or faster review of marketing applications for software products in other cases. During the pilot program, FDA customers, including pilot participants, will have the opportunity to provide input on the development of the precertification program.

DATES: FDA is seeking participation in the voluntary Software Precertification pilot program beginning August 1, 2017. See the "Participation" section for instructions on how to submit a request to participate. The voluntary Software Precertification pilot program will select up to nine participants who best match the selection criteria. This pilot program will begin

September 1, 2017.

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-2017-N-4301 for "Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification 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.gpo.gov/fdsys/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: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5458, Silver Spring MD 20993, 301-796-5528, Bakul.Patel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA recognizes that an efficient, risk-based approach to regulating digital health technology will foster innovation of digital health products. FDA's traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software products. An agile paradigm is necessary to accommodate the faster rate of development and innovation of software devices as compared to other types of devices. Traditional implementation of the premarket requirements may impede or delay patient access to critical evolutions of software technology, particularly those presenting a lower risk to patients. To evaluate a new approach toward software, FDA is launching a pilot of a precertification program for the assessment of companies that perform high-quality software design and testing. The Software Precertification (Pre-Cert) pilot program is part of FDA's ongoing efforts to develop pragmatic approaches within its existing authorities to

optimally foster the development of high-quality, safe and effective digital health products while assuring timely patient access. FDA has previously discussed the idea of a precertification program in various forums and invites further input from all stakeholders throughout this pilot. FDA intends to establish a process for company precertification that could replace the need for a premarket submission for certain products or allow for decreased submission content and/or faster review of marketing submissions for other products. CDRH plans to select its first participants and initiate the voluntary Software Pre-Cert pilot program focusing on receiving input on the activities and criteria critical to streamlining premarket review of software products by September 1, 2017.

FDA is issuing its Digital Health Innovation Action Plan.[1] The Action Plan presents FDA's vision for the regulation of digital health technologies that are medical devices and the actions FDA intends to pursue to provide greater clarity regarding what types of digital health technology are subject to regulation. In the Action Plan, FDA describes a forward-leaning approach to ensure that we will implement the right policies and regulatory tools. The Software Pre-Cert pilot program is one component of FDA's comprehensive approach to digital health medical devices described in the Action Plan. FDA welcomes comments on the policies, pathways, and regulatory tools the Agency should consider in designing a new paradigm for overseeing digital health medical devices. (See information on how to submit comments to the public docket in the ADDRESSES section.)

The Software Pre-Cert pilot will help inform the development of the Pre-Cert program for software developers, including what criteria can be used to assess whether a company consistently and reliably engages in high-quality software design and testing (validation) and ongoing maintenance of its software products. FDA and companies participating in the pilot

[1] Available at https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265.

program will explore the use of external software development standards to reduce premarket software documentation burden. Precertified companies that have demonstrated a culture of quality and organizational excellence could bring certain types of digital health products to market without FDA premarket review or after a streamlined, less-burdensome FDA premarket review. The criteria developed and evaluated for precertification during the pilot program may also be used to inform the establishment of a third-party certification program, in which third parties may facilitate the precertification of companies, and will enable greater patient access to digital health technologies and will allow the Agency to devote more resources to the evaluation of higher risk technologies/products.

Companies are eligible to participate in this voluntary Software Pre-Cert pilot program based on the criteria listed in Section A. Participation. FDA will select up to nine participants, who best match the selection criteria and who reflect the broad spectrum of software developers (e.g., both small and large software development firms). FDA intends to include companies that develop a range of products (both low and high risk) to learn how to apply the Software Pre-Cert program to different product types. FDA also intends to include companies that are not considered to be traditional medical device manufacturers, but who intend to make digital health technology.

The purpose of the Software Pre-Cert pilot is to leverage customer input to develop a program that can help reduce the time and cost of market entry for software developers that FDA determines reliably manufacture high-quality, safe and effective digital health devices. This voluntary pilot program does not represent a new requirement; instead, it is an opportunity to help FDA develop an innovative approach for digital health technology.

A. Participation

Companies that may be eligible to participate in this voluntary Software Pre-Cert pilot program are limited to those firms who follow the procedures set out in Section B and also meet the following selection qualities that follow.

1. The company must be developing or planning to develop a software product that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).
2. The company has an existing track record in developing, testing, and maintaining software products demonstrating a culture of quality and organizational excellence measured and tracked by Key Performance Indicators (KPIs) or other similar measures.
3. While participating in the pilot, the company must agree to:
    a. Provide access to measures described in selection quality number 2, listed previously (KPIs or similar measures).
    b. Collect real-world postmarket performance data and provide it to FDA.
    c. Be available for real-time consultations with FDA.
    d. Be available for site visits from FDA officials.
    e. Provide information about the firm's quality management system.

B. Procedures

To be considered for the voluntary Software Pre-Cert pilot program, a company should submit a statement of interest for participation to FDAPre-CertPilot@fda.hhs.gov. The statement of interest should include agreement to the selection qualities listed in Section A. Participation.

The following captures the proposed process for the voluntary Software Pre-Cert pilot program:

1. FDA will collect statements of interest for participation in the pilot program beginning August 1, 2017.
2. FDA will evaluate the statements of interest for participation and select no more than nine participants, who best meet the selection criteria and who reflect the broad spectrum of software developers, including companies that develop a range of products (both low and high risk). FDA will work with the selected participants to develop criteria for precertification and the types of information that should be reviewed during the precertification process or postmarket, rather than during the review of a premarket submission.
    a. Depending on the stage of development of the company's software product, FDA will work interactively with the participating company through the Q-submission process, including via Pre-Submissions, Informational Meetings, Submission Issue Meetings, etc. (Ref. 1).
3. 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 precertification program in collaboration with participants.

During this voluntary Software Pre-Cert pilot program, CDRH staff intends to be available to answer questions or concerns that may arise. The voluntary Software Pre-Cert pilot program participants will be asked to comment on and discuss their experiences with the Software Pre-Cert pilot process.

II. Beginning Date of the Software Pre-Cert Pilot Program

FDA intends to accept requests for participation in the voluntary Software Pre-Cert pilot program beginning August 1, 2017. This pilot program will begin September 1, 2017.

III. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. 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. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

IV. Reference

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

1. "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff; Guidance for Industry and Food and Drug Administration Staff," February 2014, available at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf.

Dated: July 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-15891 Filed: 7/27/2017 8:45 am; Publication Date: 7/28/2017]