diseases or other conditions (often referred to as clinical decision support software). Similar software functions may be intended for use by patients. This draft guidance provides clarity on the scope of FDA's oversight of: (1) Clinical decision support software intended for healthcare professionals, and (2) patient decision support software intended for patients and caregivers who are not healthcare professionals.

FDA recognizes that the term ''clinical decision support'' or ''CDS'' is used broadly and in different ways, depending on the context. This draft guidance defines ''CDS'' in the context of and using language from section 3060(a) of the 21st Century Cures Act (Cures Act), which amended section 520 of the FD&C Act (21 U.S.C. 360j) and excludes certain software functions from the device definition. The purpose of this guidance is to identify the types of decision support software functionalities that: (1) Do not meet the definition of a device, in light of the Cures Act; (2) may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FD&C Act, including, but not limited to, premarket clearance and premarket approval requirements; and (3) FDA intends to focus its regulatory oversight on.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Clinical and Patient Decision Support Software.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Guidance Documents/default.htm.* Guidance documents are also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Clinical and Patient Decision Support Software'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400062 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance 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 812 have been approved under OMB control number 0910–0078; 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 814, subpart H have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26439 Filed 12–7–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4301]

Fostering Digital Health Innovation: Developing the Software Precertification Program; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Fostering Digital Health Innovation: Developing the Software Precertification Program.'' The purpose of the public workshop is to discuss the progress of the pilot precertification program and to seek input on the ongoing development of the Software Precertification Program. In its Digital Health Innovation Action Plan and as part of the Medical Device User Fee Amendments, FDA has committed to explore opportunities to establish streamlined regulatory pathways tailored for digital health technologies that take into account real world evidence while incorporating principles established through international harmonization.

DATES: The public workshop will be held on January 30 to 31, 2018, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by June 29, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at Ruth L. Kirschstein Auditorium, Natcher Conference Center, Bldg. 45, National Institutes of Health (NIH) Campus, 9000 Rockville Pike, Bethesda, MD 20892. The entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center located adjacent to the Medical Center Metro, where routine security check procedures will be performed. Please visit the following Web site for NIH campus location, parking, security, and travel information: *http://www.nih.gov/about/visitor/index.htm.* Please visit the following Web site for information on the Natcher Conference Center: *http://www.genome.gov/11007522.*

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 29, 2018, at the *https://www.regulations.gov* electronic filing system. 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–2017–N–4301 for ''Fostering Digital Health Innovation: Developing the Software Precertification Program; Public Workshop; Request for Comments.'' 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 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, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993, 301–796–5528, *Bakul.Patel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), which reauthorizes the Medical Device User Fee Amendments for fiscal years 2018 through 2022, FDA has committed to explore opportunities to establish streamlined regulatory pathways tailored for digital health technologies that consider real world evidence while incorporating principles established through international harmonization. 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-based medical technologies.

FDA issued a Digital Health Innovation Action Plan on July 27, 2017, in order to outline its efforts to develop pragmatic approaches to balance benefits and risks of digital health products (Ref. 1). In the **Federal Register** of July 28, 2017, FDA announced its Software Precertification (Pre-Cert) Pilot Program (82 FR 35216). The voluntary pilot 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. 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. The pilot program began in September 2017. This public workshop provides an opportunity for FDA customers to provide input on the development of the precertification program.

II. Topics for Discussion at the Public Workshop

During the public workshop, speakers and participants will discuss a range of issues related to the Software Pre-Cert program and the development of novel premarket approval/clearance pathways for digital health products. Discussion topics include:

• Criteria and measures to assess whether a company consistently and reliably engages in high-quality software design and testing (validation) and ongoing maintenance of its software products.

○ Appropriate ''Key Performance Indicators'' that are independent of organization size, deployment strategies, or computing platforms.

• Levels of precertification and how those levels correlate to the digital health product's risk.

• Other aspects and topics related to pre-certifying a company including methods and mechanisms for a company to maintain precertification status.

• Types of digital health products that should be marketed based on the levels of precertification without FDA premarket review or after a streamlined, less-burdensome FDA premarket review.

• Considerations for streamlined premarket review and postmarket data collection and analysis.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar (*https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*) and select this event from the list of items provided. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by January 18, 2018, 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5661 or email: *Susan.Monahan@fda.hhs.gov,* no later than January 16, 2018.

Requests for Oral Presentations: During online registration, you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by January 19, 2018. All requests to make oral presentations must be received by the close of registration on January 18, 2018, 4 p.m. If selected for presentation, any presentation materials must be emailed to Maggie Fu at *maggie.fu@fda.hhs.gov* no later than January 25, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration Web page after January 23, 2018. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar (*https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*) and select this event from the list of items provided. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.*

IV. Reference

The following reference is on display at 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 addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA's Digital Health Innovation Action Plan issued on July 27, 2017 available at: *https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265.*

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26457 Filed 12–7–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6313]

Prescription Drug User Fee Act VI Commitment To Assess Current Practices of the Food and Drug Administration and Sponsors in Communicating During Investigational New Drug Development; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the statement of work to assess current practices of FDA and sponsors in communicating during investigational new drug (IND) development and identify best practices and areas of improvement. The independent assessment is part of FDA performance commitments under the recent reauthorization of the Prescription Drug User Fee Act (PDUFA). The independent assessment of current practices of FDA and sponsors in communicating during drug development is described in detail in the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022'' available at *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.* As part of FDA performance commitments described in this document, the assessment will be conducted by an independent contractor. FDA is providing for public comment on the statement of work before revising and requesting contractor proposals.

DATES: Submit either electronic or written comments by January 22, 2018.

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 January 22, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 22, 2018. 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.

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,