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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Matthew Brenner, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance for industry entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination given the upcoming deadline for product listing information updates for owners and operators of tobacco product manufacturing establishments. In addition, the compliance policy for certain product listing information updates set forth in this revised guidance presents a policy to limit submissions consistent with the public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

This revised guidance describes the compliance policy for product listing information updates for deemed tobacco products for persons who owned or operated domestic manufacturing establishments engaged in the manufacture of deemed products prior to August 8, 2016, and continued to own or operate such establishment(s) on or after August 8, 2016. With respect to the deemed tobacco products listing requirement, FDA does not intend to enforce the requirement for persons who own or operate domestic manufacturing establishments engaged in the manufacture of deemed tobacco products to update product listing information during the month of December 2017 provided they registered and listed their products by October 12, 2017.[1] As a result, registrants of deemed products would update their product listing by June 30, 2018, and complete their next annual registration by December 31, 2018. If an establishment is engaged in the manufacture of both deemed tobacco products and tobacco products originally regulated under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), FDA intends to enforce the registration and product listing information requirements for tobacco products originally regulated under the FD&C Act.

Owners or operators of establishments engaged in the manufacture of deemed products as of August 8, 2016, were first required to register and submit deemed product listing information under section 905 of the FD&C Act (21 U.S.C. 387e) by December 31, 2016. However, in a guidance issued in September 2017, FDA announced that it does not intend to enforce these requirements with respect to deemed products provided the registration and product listing submissions were received by FDA on or before October 12, 2017.

[1] Registration by such persons by October 12, 2017, satisfies the requirement in section 905(b) of the FD&C Act that such persons register their establishments annually on or before December 31, 2017.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on registration and product listing for owners and operators of domestic tobacco product establishments. 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. 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 section 905 of the FD&C Act have been approved under OMB control number 0910–0650.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26469 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–2016–D–2483]

Software as a Medical Device: Clinical Evaluation; International Medical Device Regulators Forum; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Software as a Medical Device (SaMD): Clinical Evaluation.'' This guidance was prepared as part of the FDA's international convergence efforts under the auspices of the International Medical Device Regulators Forum (IMDRF), formerly the Global Harmonization Task Force. The guidance, informed by global and U.S. public comments, pertains to Software as a Medical Device (SaMD) and focuses on principles of clinical evaluation, which include establishing the scientific validity, clinical performance, and analytical validity for SaMD. The guidance is intended to provide globally harmonized principles of when and what type of clinical evaluation is appropriate based on the risk of the SaMD.

DATES: The announcement of the guidance is published in the **Federal Register** on December 8, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2016–D–2483 for ''Software as a Medical Device (SaMD): Clinical Evaluation.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Software as a Medical Device (SaMD): Clinical Evaluation'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993–0002, 301–796–5528.

Regarding the IMDRF: Melissa A. Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5432, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities across the globe to promote international harmonization and convergence of regulatory requirements. One of the goals of global convergence is to identify and reduce differences in regulatory approaches among regulatory agencies. IMDRF seeks to advance international convergence in the approach towards medical device regulation with input from both regulatory and industry representatives. The current members of the Management Committee of the IMDRF are regulatory officials from Australia (Therapeutic Goods Administration), Brazil (National Health Surveillance Agency), Canada (Health Canada), China (China Food and Drug Administration), European Union (European Commission Directorate-General for Internal Market, Industry, Entrepreneurship, and Small and Medium-sized Enterprises), Japan (Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour, and Welfare), Russia (Ministry of Healthcare), Singapore (Health

Sciences Authority), and the United States (U.S. FDA). The World Health Organization and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee are IMDRF Official Observers. The Asian Harmonization Working Party and the Pan American Health Organization are IMDRF Affiliate Organizations.

The IMDRF Management Committee (IMDRF MC) chartered the SaMD Working Group (WG) to develop a regulatory framework for SaMD and to develop converged principles for global regulators to adopt in their respective jurisdictions. The SaMD WG includes representatives from the IMDRF members, industry, academia, and other key stakeholders as well as regional harmonization initiatives from around the world.

The IMDRF SaMD WG considered comments received on the draft guidance that was announced in the **Federal Register** of October 14, 2016 (81 FR 71105). The SaMD WG also considered public comments received by other regulators and from other global stakeholders. The final IMDRF/SaMD WG/N41 document, ''Software as a Medical Device (SaMD): Clinical Evaluation,'' submitted to IMDRF MC was revised appropriately in response to all of the comments. The IMDRF MC in Ottawa, Canada, at the 12th meeting held from September 19 to 21, 2017, unanimously approved the document entitled ''Software as a Medical Device (SaMD): Clinical Evaluation.'' This final IMDRF/SaMD WG/N41 document is available for regulatory implementation according to the regulatory process in each jurisdiction.

This guidance adopts the internationally converged principles agreed upon by the IMDRF. FDA adoption of these principles provides FDA with an initial framework when further developing the Agency's specific regulatory approaches and expectations for regulatory oversight. This guidance does not provide recommendations for FDA Staff and Industry to apply to specific regulatory situations, nor does it modify current regulatory expectations, including those for regulatory submissions, at this time. FDA intends to consider the principles of this guidance in the development of regulatory approaches for SaMD and digital health technologies. In developing regulatory approaches based on the principles of this guidance, the Agency intends to follow a public process, including providing opportunities for public input. For more information on FDA adoption of IMDRF documents as an FDA guidance document, please see *https://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/default.htm.*

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Software as a Medical Device (SaMD): Clinical Evaluation.'' 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 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/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Software as a Medical Device (SaMD): Clinical Evaluation'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16039 to identify the guidance you are requesting.

Dated: December 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26441 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–2016–N–3083]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), the Food and Drug Administration (FDA or Agency) is required to report annually in the **Federal Register** on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct.

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

A. Postmarketing Requirements and Commitments

A PMR is a study or clinical trial that an applicant is required by statute or regulation to conduct postapproval. A PMC is a study or clinical trial that an applicant agrees in writing to conduct postapproval, but that is not required by statute or regulation. PMRs and PMCs can be issued upon approval of a drug [1] or postapproval, if warranted.

FDA can require application holders to conduct postmarketing studies and clinical trials:

- To assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a drug product (section 505(o)(3) of the FD&C Act (21 U.S.C. 355(o)(3)), as added by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85)).
- Under the Pediatric Research Equity Act (PREA) (Pub. L. 108–155), to study certain new drugs for pediatric populations, when these drugs are not adequately labeled for children. Under section 505B(a)(3) of the FD&C Act (21 U.S.C. 355c), the initiation of these studies may be deferred until required safety information from other studies in adults has first been submitted and reviewed.
- To verify and describe the predicted effect or other clinical benefit for drugs approved in accordance with the accelerated approval provisions in section 506(c)(2)(A) of the FD&C Act (21

[1] For the purposes of this notice, references to ''drugs'' or ''drug products'' include drugs approved under the FD&C Act and biological products licensed under the Public Health Service Act other than biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).