data systems used for the electronic transfer, storage, display, or conversion of medical device data; medical image storage devices, used to store or retrieve medical images electronically; medical image communications devices, used to transfer medical image data electronically between medical devices; software that automates laboratory workflow; and low-risk general wellness products. FDA intends to provide clarification of its interpretation of section 520(o)(1)(E) of the FD&C Act, which is for software functions intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of disease or other conditions (often referred to as clinical decision support software) in a separate guidance document. Section 520(o)(2) of the FD&C Act describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device. FDA also intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act.'' 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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/GuidanceDocuments/default.htm.* Guidance documents are also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17030 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 820 have been approved under OMB control number 0910–0073; 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 803 have been approved under OMB control number 0910–0437; 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. 2017–26442 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–2009–D–0508]

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (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.

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–2009–D–0508 for ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' 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)).

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]

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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.