comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993, 301–796–2400; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 1, 2015 (80 FR 31050), FDA announced the availability of a draft guidance for industry entitled ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' Interested persons were originally given until July 31, 2015, to comment on the draft guidance. The Agency believes that reopening the comment period for an additional 90 days from the date of publication of this notice will allow adequate time for interested persons to submit comments without significantly delaying Agency decision-making on these important issues.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: September 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25356 Filed 10–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3402]

Electronic Submission of Final Approved Risk Evaluation and Mitigation Strategies and Summary Information in a Standard Structured Product Labeling Format; Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of pilot project, request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a pilot project for the submission of final approved Risk Evaluation and Mitigation Strategies (REMS) and certain REMS summary information electronically in a standard Structured Product Labeling (SPL) format. Participation in the pilot is voluntary and is open to application holders of drugs with REMS. The pilot is intended to help application holders, FDA, and other interested stakeholders evaluate a potential approach to converting REMS into SPL format and evaluate the usefulness of the REMS information to be provided in SPL format. This project also will help provide FDA with feedback on these topics from pilot participants and other interested stakeholders.

DATES: Submit requests to participate in the REMS SPL pilot from October 6, 2015 to December 7, 2015. See the ''Participation'' section for instructions on how to submit a request to participate. The pilot will proceed for 4 months, from October 6, 2015 to February 3, 2016. This pilot may be extended as resources and needs allow.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–3402 for ''Electronic Submission of Final Approved Risk Evaluation and Mitigation Strategies and Summary Information in a Standard Structured Product Labeling Format; Pilot Project.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Adam Kroetsch at *REMS_Standardization@fda.hhs.gov* or at 301–796–3842.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a pilot project for the submission of final approved REMS and certain REMS summary information electronically in an SPL format. This pilot is being conducted as a part of the ''Pharmacy Systems Under REMS Project: Standardizing REMS Information for Inclusion Into Pharmacy Systems Using Structured Product Labeling (SPL).'' More information on this project—one of four predefined priority projects that are a part of the larger REMS Integration Initiative—can be found in the report ''Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)'' (the REMS report) (*http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM415751.pdf*). FDA intends to eventually make REMS in SPL format accessible to the public via a free, publicly available Web site.

As described in the REMS report, stakeholders have expressed concern that information about REMS materials, tools, and requirements are not communicated to stakeholders in a clear and consistent manner. They also have told FDA that REMS materials and requirements may be difficult to locate, and specific activities and requirements of various stakeholders (*e.g.*, prescriber, pharmacist) are not clearly outlined. Furthermore, some stakeholders have difficulty integrating REMS materials and procedures into their existing health information systems and healthcare delivery processes. Because of these factors, stakeholders reported spending excessive time trying to locate, understand, and comply with different REMS requirements. (For more general background information on REMS, as well as a more comprehensive discussion of the issues mentioned in this paragraph, please refer to the Background Materials (*http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM362078.pdf*) for the July 2013 REMS Standardization and Evaluation Public Meeting.)

To help address the problems described in the previous paragraph of this document, FDA committed to develop a standardized REMS format that can be included in SPL. FDA believes that this project, when completed, will address many of the concerns described previously regarding REMS because SPL information can be easily shared and made available online, and is readily incorporable into health information technology. Furthermore, FDA and application holders are both familiar with SPL and possess much of the institutional knowledge needed to create and disseminate files in this format. Ultimately, SPL can serve as a conduit of structured REMS information to healthcare providers and patients, while also providing accessible information about what requirements exist and who is responsible for their completion. SPL may also promote efficiency in the development and review of REMS documents.

II. About the REMS SPL Pilot

For all REMS programs (both REMS with and without elements to assure safe use (ETASU)) included in the pilot, the REMS document will be captured using standardized section headings. More information about the REMS document is available in FDA's draft guidance for industry ''Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications'' (*http://www.fda.gov/downloads/Drugs/.../Guidances/UCM184128.pdf*). For REMS with ETASU, the SPL will include additional information about the requirements these ETASU impose. This information is captured in two places: A human-readable ''REMS Summary'' (described in detail in ''The REMS Summary'' section of this document) and associated machine-readable data elements. Both the REMS Summary and the data elements will capture four basic pieces of information about each requirement:

- *Who* is required to carry out the requirement: For example, a requirement may be carried out by the healthcare provider who prescribes the drug or dispenses it.
- *What* that individual is required to do: This could include a clinical activity, such as counseling a patient, or an administrative one, such as completing an enrollment form.
- *When* the activity must be carried out: For example, a REMS activity may need to be completed before a drug is prescribed or dispensed, or before a patient is able to receive the drug.
- *References* to REMS materials that may contain additional information about the requirement, such as forms and educational materials.

For REMS approved as a shared system, the REMS information submitted in SPL format should be identical for each product in the shared system.

A. The REMS Summary

For REMS with ETASU, the REMS Summary will be presented in a tabular format that facilitates coding of REMS data elements and allows stakeholders to quickly obtain a reader-friendly overview of what the REMS requires. It uses language that is similar to that found in existing REMS documents and the summaries found on FDA's REMS Web site (*http://www.fda.gov/REMS*). Detailed instructions for creating the REMS Summary are available in the Draft REMS SPL Implementation Guide Excerpt on FDA's SPL Web site (*http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm)*. The REMS Summary does not replace the approved REMS document, which will continue to be the enforceable document establishing the REMS requirements.

B. REMS Data Elements

For REMS with ETASU, the REMS data elements describe REMS requirements using a standardized, machine-readable format that permits integration of REMS information into electronic health information technology, including clinical decision support, e-Prescribing systems, and electronic pharmacy systems. FDA has developed terminology to assist in the coding of REMS data elements. This terminology is available as part of the Draft REMS SPL Implementation Guide Excerpt on FDA's SPL Web site (*http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm).* The REMS Data Elements do not replace the approved REMS document, which will continue to be the enforceable document establishing the REMS requirements.

III. How To Participate in the REMS SPL Pilot

A. Participation

Volunteers interested in participating in the pilot should contact pilot staff by email at *REMS_Standardization@fda.hhs.gov.* The following information should be included in the request: Contact name, contact phone number, and contact email address. FDA will contact interested applicants to discuss the pilot. FDA is seeking a limited number of participants (no more than nine) to participate in this pilot. FDA is also seeking comment from any stakeholder on its proposed approach for capturing REMS information in SPL format in this pilot, as described in section II.

B. Procedures

To create an SPL file and submit it to FDA, a participant will need the following tools: Appropriate software, knowledge of terminology and standards, and access to FDA's Electronic Submissions Gateway (ESG) (*http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*). The ESG is an Agency-wide means of accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory submissions. Instructions and information regarding the creation of an SPL file and the converting of REMS information into SPL can be found at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm*. There should be no additional cost associated with obtaining the software. In 2010, FDA collaborated with Pragmatic Data, LLC (*http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm*), to make available free SPL authoring software that SPL authors may use to create new SPL documents or edit previous versions.

After the SPL is created, the participant would upload the file through the ESG. The Internet portal can be found at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*. Prior to uploading an SPL file, one must obtain a digital certificate. Instructions regarding obtaining a digital certificate used with FDA's ESG and uploading the SPL file for submission can be found at *http://www.fda.gov/esg/default.htm*. The digital certificate binds together the owner's name and a pair of electronic keys (a public and a private key) that can be used to encrypt and sign documents. A fee of up to approximately $20 is charged for the digital certificate. Application holders should have already secured a digital certificate because they are required to do so when they register and list.

During the pilot, FDA staff will be available to answer any questions or concerns that may arise. Pilot participants will be asked to comment on and discuss their experiences converting their REMS into SPL format. Their comments are expected to assist FDA in its completion of the REMS SPL project.

IV. Duration of the REMS SPL Pilot

FDA will accept requests for participation in the REMS SPL pilot from October 6, 2015 to December 7, 2015. The pilot will proceed for 4 months, from October 6, 2015 to February 3, 2016. This pilot may be extended as resources and needs allow.

V. 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 314 have been approved under OMB control number 0910–0001.

Dated: September 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25349 Filed 10–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–1064, FDA–2015–M–1065, FDA–2015–M–1177, FDA–2015–M–1178, FDA–2015–M–1325, FDA–2015–M–1326, FDA–2015–M–1460, FDA–2015–M–1461, FDA–2015–M–1557, FDA–2015–M–1708, FDA–2015–M–1709, FDA–2015–M–1956, FDA–2015–M–1957, FDA–2015–M–1958, FDA–2015–M–1959, FDA–2015–M–2077, FDA–2015–M–2078, FDA–2014–M–2247]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that