4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-E-4282]

Providing Regulatory Submissions in Electronic Format--Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling." This draft guidance is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require that certain submissions under the FD&C Act and the Public Health Service Act (PHS Act) be submitted in electronic format, beginning no earlier than 24 months after issuance of final guidance on electronic format for submissions. The draft guidance describes how FDA plans to implement the requirements for the electronic submission of Risk Evaluation and Mitigation Strategies (REMS) documents in certain submissions under new drug applications, abbreviated new drug applications, and biologics license applications, beginning no earlier than 24 months after issuance of the final guidance.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-2017-E-4282] for " Providing Regulatory Submissions in Electronic Format--Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling; Draft Guidance for Industry; Availability." 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 office 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 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 to the 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Adam Kroetsch, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 1168, 10903 New Hampshire Ave, Silver Spring, MD 20993-0002, 301-796-3842; or Aaron Sherman, Center for Drug Evaluation

and Research, Food and Drug Administration, Bldg. 51, rm. 6366, 10903 New Hampshire Ave, Silver Spring, MD 20993-0002, 240-402-0493; 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

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling; Draft Guidance for Industry." FDASIA (Pub. L. 112-144), amended the FD&C Act to add section 745A (21 U.S.C. 379k-1), entitled "Electronic Format for Submissions." Section 745A(a)(1) of the FD&C Act requires that submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the PHS Act (42 U.S.C. 262(a) or (k)) be submitted to FDA in electronic format no earlier than 24 months after FDA issues final guidance on electronic format for submissions. In accordance with section 745A(a)(1) of the FD&C Act, FDA is issuing this draft guidance, announcing its determination that submission types identified in the guidance must be submitted electronically in the format specified in the guidance beginning 24 months after the issuance of the final guidance.

This draft guidance (and the technical specification documents it references) describes how certain REMS documents will be required to be submitted in electronic format using Structured Product Labeling (SPL) as outlined in the FDA "Structured Product Labeling (SPL) Implementation Guide with Validation Procedures" (available at http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM321

876.pdf). (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.) SPL is a Health Level 7 data standard used by FDA since 2005. For more information on how FDA interprets section 745A(a) of the FD&C Act, see the guidance for industry "Providing Regulatory Submissions in Electronic Format--Submissions Under Section745A(a) of the Federal Food, Drug, and Cosmetic Act" (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM384686.pdf).

Development of this guidance was facilitated by completion 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)" (available at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM415751.pdf).

II. 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.

III. Electronic Access

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

Dated: August 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-18506 Filed: 9/1/2017 8:45 am; Publication Date: 9/5/2017]