4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6231]

Use of a Drug Master File for Shared System Risk Evaluation and Mitigation Strategy Submissions; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Use of a Drug Master File for Shared System REMS Submissions." The draft guidance provides information to applicants who are part of a shared system Risk Evaluation and Mitigation Strategy (REMS) on using an electronic Type V Drug Master File (DMF). FDA recommends that applicants who are part of a shared system REMS use a Type V DMF for their REMS submissions to improve the efficiency of the submission and review process.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-D-6231 for "Use of a Drug Master File for Shared System REMS Submissions; 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 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gita Toyserkani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2422, Silver Spring, MD 20993-0002, 301-796-1783, Gita.Toyserkani@fda.hhs.gov; 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 "Use a of Drug Master File for Shared System REMS Submissions."

A REMS is a required risk management plan that uses tools beyond the FDA-approved prescribing information to ensure that the benefits of certain drugs outweigh their risks (see section 505-1 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355-1)).

FDA can, under certain circumstances, require that the REMS for a drug include one or more elements to assure safe use (ETASU) (see section 505-1(f) of the FD&C Act). When ETASUs are required for an innovator drug, any abbreviated new drug application (ANDA) referencing that innovator drug must use an shared system REMS with the innovator (unless FDA waives the requirement for using a shared system) (see section 505-1(i) of the FD&C Act). There are also circumstances under which multiple applicants form an SSR to minimize the burden on the health care delivery system, such as for a class of similar products.

Under a shared system REMS, multiple applicants should coordinate the submission of identical documents to their respective applications. To improve the efficiency of the submission and review process for shared system REMS, FDA recommends that applicants who are part of a shared system REMS use a Type V DMF for their REMS submissions. A DMF is a submission to the Agency that may be used to provide confidential detailed information to the Agency. Among other things, a DMF allows the DMF holder to authorize other applicants to reference information in the holder's DMF. A DMF is submitted solely at the discretion of the DMF holder, and the technical contents of a DMF are customarily reviewed by FDA only in connection with the review of an application.

The use of a DMF is not a requirement for shared system REMS. However, if shared system REMS applicants choose to use the DMF option for their shared system REMS submissions, this guidance (and the technical conformance guide that supplements it, available at https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm535180.htm) is intended to provide an overview of the approach for doing so. Also, if shared system REMS applicants choose to use the DMF option, as of the date specified by FDA, they must submit the DMF in the Electronic Common Technical Document format, as

previously stated in the guidance for industry "Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 4)" (available at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm).

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 use of a DMF for submission of shared system REMS. 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.

II. 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 314.50 have been approved under OMB control number 0910-0001; the collections of information in 21 CFR 314.70 have been approved under OMB control number 0910-0001; the collections of information in 21 CFR 201.57 have been approved under OMB control number 0910-0572; the collections of information in 21 CFR 314.420 have been approved under OMB control number 0910-0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

or

https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: November 2, 2017.

Lauren Silvis,

Chief of Staff.

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