4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0461]

# Format and Content of a Risk Evaluation and Mitigation Strategy Document; Revised Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled "Format and Content of a REMS Document." A Risk Evaluation and Mitigation Strategy (REMS) document, which is part of a REMS that is required by FDA, establishes the goals and requirements of the REMS. This revised draft guidance describes a new recommended format for a REMS document. The new format was developed based on extensive stakeholder feedback. This guidance revises and supersedes the draft guidance entitled "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications," that was published by FDA on October 1, 2009.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2009-D-0461 for "Format and Content of a REMS Document." 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, 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 revised draft guidance for industry entitled "Format and Content of a REMS Document." The Food and Drug Administration Amendments

Act of 2007 (Pub. L. 110-85) created section 505-1 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355-1), which authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks (see section 505-1(a) of the FD&C Act). A REMS is a required risk management strategy that can include one or more elements to ensure that the benefits of a drug outweigh its risks (see section 505-1(e) of the FD&C Act). The REMS document includes concise information about the goals and requirements of the REMS as they relate to the elements described under the FD&C Act.

In the *Federal Register* of October 1, 2009 (74 FR 50801), FDA announced the availability of a draft guidance for industry entitled "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications." The 2009 draft guidance described the recommended format and content for submission of proposed REMS. It also included information and recommendations on the content of assessments and proposed modifications of approved REMS.

Over the last 6 years, under the REMS Integration Initiative, FDA's implementation of the REMS authorities has evolved. The goals of the REMS Integration Initiative included developing guidance, improving standardization and assessment of REMS, and improving integration of REMS into the health care system. (More information on the REMS Integration Initiative can be found at: https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm350852.htm).

Through the REMS Integration Initiative and other outreach, FDA has received feedback that specific activities and requirements for various stakeholders (e.g., prescribers, pharmacists)

are not clearly communicated in REMS documents. Stakeholders have reported spending excessive time trying to locate, understand, and comply with REMS requirements.

To address the stakeholders' feedback, FDA is revising the 2009 draft guidance on the format and content of a REMS to include information to assist applicants in drafting clear, informative, and standardized REMS documents. This revised draft guidance provides updated recommendations on the format and content of a REMS document and supersedes the 2009 draft guidance. Additional and more detailed information is provided in the template appended to this guidance.

The new format of the REMS document, as described in this revised draft guidance and appended template, contains substantially the same content as described in the 2009 draft guidance; however, the information has been reorganized. In the old format, the REMS requirements were organized by the elements described in the statute. In the new format, requirements are organized to describe who is responsible for implementing the requirement, when the requirement is to be implemented, what the required action is, and with what REMS material(s). Additionally, the new format supports submission of REMS documents in Structured Product Labeling (SPL) format.

Certain information included in the 2009 draft guidance has been revised and included in other guidances subsequently published and therefore has been omitted from this revised draft guidance. For example:

- Information on how FDA determines when a REMS is necessary to ensure that the benefits of a drug outweigh its risks can be found in the draft guidance for industry, "FDA's Application of Statutory Factors in Determining When a REMS Is

Necessary" (at: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm521504.pdf).

- Information on REMS modifications can be found in the guidance for industry, "Risk Evaluation and Mitigation Strategies: Modifications and Revisions" (at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm441226.pdf).

This revised guidance and appended template are being reissued in draft form to enable the public to review and comment before finalization.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on the format and content of a REMS document. 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. The Paperwork Reduction Act of 1995

This revised draft guidance contains information collection provisions that 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 collection of information in the guidance was approved under OMB control numbers 0910-0001 and 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,

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

Dated: October 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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