and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993–0002, 301–796–5333, email: *cderdatastandards@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 committed to achieve the long-term goal of improving the predictability and consistency of the electronic submission process, and enhancing transparency and accountability of FDA information technology related activities. FDA agreed in the PDUFA VI commitment letter to hold annual public meetings to seek stakeholder input related to electronic submissions and data standards to inform the FDA IT Strategic Plan and published targets. The commitment letter outlines FDA's performance goals and procedures under the PDUFA program for the years 2018–2022. The commitment letter can be found at *https://www.fda.gov/forindustry/userfees/prescriptiondrug userfee/ucm446608.htm.*

II. Topics for Discussion at the Public Meeting

FDA strives to achieve a fully automated standards-based IT environment that enhances the regulatory review processes for human drugs and biologics. The purpose of the March 21, 2018, public meeting is to obtain input from industry and other interested stakeholders on enhancing the transparency and accountability of the electronic submission and data standards activities. To help fulfill its commitment, FDA is particularly interested in receiving input on the following topics:

- Electronic Submissions
  - Electronic submission process, including key electronic submission milestones and associated sponsor notifications from the completion of the upload of the submission to the Electronic Submissions Gateway (ESG) through the time the submission is made available to the review team.
  - Electronic submission system past performance, emerging industry needs, and technology initiatives.
  - Published and future targets for the ESG and related electronic submission systems.
  - Implementation of electronic Common Technical Document (eCTD) v4.0.
- Data Standards Initiatives
  - International Organization for Standards (ISO) Identification of Medicinal Products (IDMP): ISO IDMP standards implementation will support a variety of regulatory activities related to development, registration, and life cycle management of medicinal products, as well as pharmacovigilance and risk management. There are five standards that describe the substance (ISO 11238), dosage form and routes of administration (ISO 11239), units of measure (ISO 11240), medicinal product identifier (ISO 11615), and pharmaceutical product identifier (ISO 11616).
  - Individual Case Safety Reports (ICSRs): ICSRs provide a consistent approach to the creation and review of drug and biologics safety information and pharmacovigilance activities.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**).

III. Participating in the Public Meeting

Registration: To register to attend ''Prescription Drug User Fee Act VI; Electronic Submissions and Data Standards; Public Meeting; Request for Comments'' please send an email to *cderdatastandards@fda.hhs.gov* by February 19, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by February 19, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Chenoa Conley, 301–796–0035, email *Chenoa.Conley@fda.hhs.gov* at least 7 days before the meeting.

Request for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session and which topic(s) you wish to address. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by March 6, 2018. All requests to make oral presentations must be received by the close of registration on February 19, 2018, midnight Eastern Time. If selected for presentation, any presentation materials must be emailed to *cderdatastandards@fda.hhs.gov* no later than March 14, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/forindustry/userfees/prescriptiondrug userfee/ucm446608.htm.*

Dated: October 5, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–21981 Filed 10–11–17; 8:45 am]

BILLING CODE 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 December 11, 2017 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.

[FR Doc. 2017–22050 Filed 10–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5868]

Requests for Reconsideration at the Division Level Under the Generic Drug User Fee Act; 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 ''Requests for Reconsideration at the Division Level Under GDUFA.'' This guidance provides recommendations for industry on the procedures for resolving scientific and/or regulatory issues or matters between FDA and applicants of abbreviated new drug applications (ANDAs) that wish to pursue a request for reconsideration within the review discipline at the division level or original signatory authority. This guidance also provides information for applicants to consider before pursuing a request for reconsideration, procedures for submitting a request for reconsideration, and the Agency's process for responding to those requests.

DATES: Submit either electronic or written comments on the draft guidance by December 11, 2017 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–