



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0502]

Risk Evaluation and Mitigation Strategies: Understanding and Evaluating Their Impact on the Health Care Delivery System and Patient Access; Public Meeting, Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA or Agency) is announcing a public meeting entitled "Risk Evaluation and Mitigation Strategies (REMS): Understanding and Evaluating Their Impact on the Health care Delivery System and Patient Access". The purpose of the public meeting is to engage in constructive dialogue and information sharing among regulators, the scientific community, the pharmaceutical industry, public health agencies, patients, patient advocates, health care system administrators, prescribers, dispensers, hospitals, infusion centers, health informatics experts, third-party payers, distributors, and the general public concerning the impact of REMS on the health care delivery system, including the impact on patients and health care providers. The discussion will focus on strategies for characterizing and evaluating the impact of REMS on the health care delivery system and on patient access to drugs subject to REMS.

The primary focus of this meeting will be on REMS with Elements to Assure Safe Use (ETASU); however, the meeting will also include discussion of issues that may apply to all

REMS. The input from this meeting and the public docket comments will be used to inform ongoing Agency initiatives related to optimizing REMS design, implementation, and assessment.

Dates and Times: The meeting will be held on October 5, 2015, from 8 a.m. to 5 p.m. and October 6, 2015, from 8 a.m. to 1 p.m.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please visit

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Please arrive early to ensure time for parking and security screening.

Contact Persons For meeting background and content: Megan Moncur, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, REMSMeetingOct2015@fda.hhs.gov.

For registration, oral presentations, special accommodations, and other meeting logistics: Cherice Holloway, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, Phone 301-796-4909, FAX: 301-796-9832, cherice.holloway@fda.hhs.gov.

Registration and Requests for Oral Presentations: Registration is free and available on a first-come, first-served basis. You must register by September 21, 2015. Seating is limited, so register early. FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the meeting will be available. To register for this meeting, please visit FDA's Drugs News & Events--Meetings, Conferences, & Workshops

calendar at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm> and select this meeting from the events list. If you need special accommodations because of a disability, please contact Cherice Holloway (see [Contact Persons](#)) at least 7 days before the meeting. Those without Internet access should contact Cherice Holloway to register.

This meeting includes public comment sessions in which FDA is seeking input on improved approaches for understanding, evaluating, and minimizing burden on the health care delivery system to the extent practicable and for helping to assure patient access to drugs that are subject to REMS. If you would like to present during a session, please identify the topic(s) you will address during registration (see section II).

FDA will do its best to accommodate requests to speak. FDA urges individuals and organizations with common interests to coordinate and/or request time for a joint presentation. Following the close of registration, FDA will allot time for each presentation and notify presenters by September 28, 2015. Do not present or distribute commercial or promotional material during the meeting. Registered presenters should check in at the registration desk before the meeting.

Live Webcast of the Meeting: To view the Connect Pro Webcast of this meeting, you must register online by 4 p.m., September 21, 2015. Webcast connections are limited, so register early. Organizations should register all viewers but access the Webcast using one connection per location.

Webcast viewers will be sent system requirements after registration and will be sent connection information after September 28, 2015. Visit https://collaboration.fda.gov/common/help/en/support/meeting_test.htm for the Connect Pro Connection Test. To get a quick overview of Connect Pro, visit

http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this notice but is not responsible for any subsequent address changes after this document publishes in the Federal Register.)

Comments: FDA is holding this public meeting to obtain information on improved strategies for evaluating and minimizing the burden of REMS on the health care delivery system to the extent practicable and their impact on patient access to the drugs covered by such programs. FDA is opening a public docket for comments to be submitted to the Agency on the issues and questions presented during the meeting. Regardless of attendance at the public meeting, interested persons may submit electronic or paper comments to FDA's Division of Dockets Management by November 2, 2015.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Send only one set of comments. Identify all comments with the docket number found in brackets in the heading of this document. When addressing specific topics (see section II), please identify the topic. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. The transcript may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hard copy or on CD-ROM after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

This meeting builds on prior stakeholder feedback on the design, implementation, and assessment of REMS, including feedback obtained through public meetings, stakeholder outreach, and comments to the public docket, including the recommendations and suggestions recently summarized in the Agency's report entitled "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies" (the Standardizing and Evaluating REMS Report)¹. The report also describes the Agency's findings concerning strategies to standardize REMS, where appropriate, with the goal of reducing the burden of implementing REMS on health care providers, patients, and others in various health care settings.

The Agency seeks to build on this foundation by updating stakeholders and obtaining their feedback on some of our current and proposed initiatives aimed at anticipating and minimizing REMS' burden on the health care delivery system, helping to assure access to drugs that are subject to REMS with ETASU, and obtaining stakeholder recommendations on additional approaches to accomplish these goals. The Agency recognizes that REMS can impose burden on the health care delivery system. The statute requires ETASU to be commensurate with the specific serious risks listed in a drug's labeling, and, considering such risks, not be unduly burdensome on patient access to the drug, and, to the extent practicable, to minimize burden on the health care delivery system. We are also seeking input on the methods for evaluating REMS' burden on the health care delivery system and their impact on patient access to drugs.

¹ In the Federal Register of September 23, 2014 (79 FR 56816), FDA published a notice announcing the availability of this draft report. The report is available at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm415751.pdf>.

The primary focus of this meeting will be on REMS with ETASU see section 505(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1(f)); however, the meeting will also include discussion of issues that may apply to all REMS.

II. Who Is the Target Audience and Who Should Attend This Public Meeting?

This meeting is open to all interested parties. The target audience is comprised of regulators, the scientific community, the pharmaceutical industry, public health Agencies, patients, patient advocates, health care system administrators, prescribers, dispensers, hospitals, infusion centers, health informatics experts, third-party payers, distributors, and the general public who are interested in providing input on approaches for both anticipating and minimizing health care delivery system burden and for helping to assure patient access to drugs that are subject to REMS, as well as those interested in improving the approaches used to evaluate the burden of REMS on the health care delivery system and their impact on patient access.

III. What Are the Topics We Intend to Discuss at the Public Meeting?

The meeting will include panel discussions and individual presentations. The main questions that will be considered are as follows: (1) How to anticipate and minimize the burden of REMS on the health care delivery system and patient access; and (2) how to improve the quality and effectiveness of methods used to evaluate REMS' burden on the health care delivery system and impact on patient access.

FDA will begin the meeting by soliciting feedback regarding how stakeholders, such as patients and health care providers, think about burden related to REMS. The meeting will then focus on strategies for anticipating and addressing REMS burden and access issues in several broad topic areas (including several areas identified in the key opinions and recommendations from stakeholders in the Standardizing and Evaluating REMS Report). Potential discussion

topics are described in this document. For topics related to strategies for minimizing burden and barriers to patient access (topics 1-3), FDA will present ongoing and planned Agency initiatives, solicit feedback on these initiatives, and ask for feedback on other opportunities for anticipating and minimizing burden and patient access issues.

Potential topics for discussion include the following:

- Topic 1: Understanding the stakeholder perspective

Discussion will focus on gaining a better understanding of how stakeholders, such as patients, health care providers, dispensers, and others, think about burden and access issues related to REMS--for example, understanding the different dimensions of burden (e.g., administrative, logistical, workflow) and better understanding the different types of patient access issues that are implicated by REMS.

- Topic 2: Improved communication about the existence of a REMS and about what is required of stakeholders under that REMS

Discussion will focus on strategies to improve communications about REMS, including communications about the existence of a particular REMS or the requirements under a particular REMS program, and how to improve the clarity of REMS materials.

- Topic 3: Improved integration of activities required under a REMS

Discussion will focus on two closely related subtopics: (1) Strategies to improve the integration of REMS requirements into the health care delivery system through process improvement (e.g., streamlining REMS processes that have an impact on stakeholder workflow or the care process, and reducing redundancies by leveraging existing training or certification requirements to meet REMS requirements); and (2) strategies to integrate

REMS into electronic health care systems (e.g., electronic health records, decision support systems, and pharmacy management systems).

- Topic 4: Improved methods for measuring the burden of REMS on the health care delivery system and the impact on patient access

Discussion will focus on identifying the most effective methods for evaluating the burden of REMS on the health care delivery system and the impact on patient access, with a goal of not only characterizing and quantifying these effects, but also identifying opportunities for improvements to a REMS program and better understanding the effect of changes to a program. This may include discussion of how to address methodological challenges in the measurement of burden and access, and how to incorporate stakeholder input into REMS design and assessment.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the public meeting, and the background material will be posted on FDA's Web site after the meeting at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm>, and to the docket at <http://www.regulations.gov>.

Dated: July 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-18149 Filed: 7/23/2015 08:45 am; Publication Date: 7/24/2015]