4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Report on the Standardization of Risk Evaluation and Mitigation Strategies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)". This report describes the Agency's findings concerning strategies to standardize risk evaluation and mitigation strategies (REMS), where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various health care settings. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA has committed to standardizing REMS to better integrate them into the existing and evolving health care system. FDA is publishing this report to allow the public to provide comment on the report as it relates to PDUFA.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft report to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 report.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Richard Currey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6125, Silver Spring, MD 20993-0002, 301-796-3918, FAX: 301-595-7910, email: REMS_Standardization@fda.hhs.gov; or Adam Kroetsch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1192, Silver Spring, MD 20993-0002; 301-796-3842, FAX: 301-847-8443, email: REMS_Standardization@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft report entitled "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)." This report describes the Agency's findings concerning strategies to standardize REMS, where appropriate, with the goal of reducing the burden on practitioners, patients, and others in various health care settings. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), enacted on September 27, 2007, established FDA's authority to require REMS for prescription drug and biological products when it determines that such a strategy is necessary to ensure that the benefits of a drug outweigh the risks. Since that time, REMS have become a key tool in augmenting FDA's drug safety capacities. The Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), enacted on July 9, 2012, amended FDA's REMS

authorities and strengthened the Agency's ability to safeguard and advance public health. Among other things, FDASIA reauthorized the Prescription Drug User Fee Act (known as "PDUFA V," reflecting the fifth reauthorization of PDUFA). As part of its PDUFA V commitments, FDA agreed, among other things, to "measure the effectiveness of REMS and standardize and better integrate REMS into the health care system." To this end, "FDA will … continue to develop techniques to standardize REMS and with stakeholder input seek to integrate them into the existing and evolving (e.g., increasingly electronic) health care system." FDA also agreed to hold one or more public meetings to explore strategies to standardize REMS, where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various health care settings, and to issue a report of the Agency's findings identifying at least one priority project with a work plan for project completion in the areas of pharmacy systems, prescriber education, providing benefit-risk information to patients, and practice settings.

FDA held a 2-day public meeting on REMS Standardization and Assessment on July 25-26, 2013, on approaches to standardizing REMS and better integrating them into the health care delivery system. A transcript of the public meeting and a background document, as well as FDA presentations made at the meeting, are available on FDA's Web site at http://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm351029.htm.

This report summarizes stakeholder engagement achieved in fiscal year (FY) 2013, including suggestions and recommendations received from meetings, an expert panel workshop, and comments received electronically (posted to a Federal docket) and via teleconferences. Stakeholder feedback guided the Agency in selecting four priority projects within the areas specified by PDUFA V: (1) Providing benefit/risk information to patients, (2) prescriber

education, (3) pharmacy systems, and (4) practice settings. This report briefly reviews the background and context for REMS as well as FDA initiatives for REMS administration and program improvement, summarizes key feedback from stakeholders and experts, and presents the design and the proposed workplans of projects in the four designated priority areas.

II. Draft Report Describing Findings Concerning REMS Standardization and Plans for Projects to Standardize REMS

A. Stakeholder Recommendations

Stakeholder input and recommendations received by FDA in 2013 emphasize the need for better communication by FDA about REMS, improved leveraging of information technology, and flexibility to tailor REMS programs to specific health care settings. The four priority projects that are discussed in detail at the end of the report flow, in part, from these recommendations, and represent the Agency's next steps toward an improved and integrated REMS strategy.

FDA found that stakeholders in various settings have successfully implemented REMS requirements, in some cases developing systems to manage REMS requirements specific to their institutions and integrate the REMS into their practices. However, FDA also heard that REMS programs affect specific stakeholder responsibilities and organizational structures differently, presenting a central challenge to standardizing REMS while meeting the needs of multiple stakeholders across an array of health care environments. Stakeholders indicated that they want flexibility to implement a REMS program based upon the nature of the health care setting.

Stakeholders emphasized that communication by FDA about REMS should be improved. They stated that FDA communications about REMS are often inadequate, inconsistent, unclear, or too difficult to access, navigate, and digest.

Stakeholders recommended that FDA create more comprehensive, evidence-based, and organized communications that can function within existing health care systems; deliver clear, actionable information to clinicians; and help to ensure that patients receive the drugs they require with excellent safety monitoring and oversight. They frequently suggested that FDA invest in and improve leveraging of existing information technology systems to better integrate REMS into standard medical practice and ongoing health care delivery.

Several stakeholders noted that current REMS documentation is not standardized and generally cannot be easily searched, queried, or managed. They recommended Structured Product Labeling (SPL) as a possible designated standard that may allow for a centralized, standardized REMS information repository.

Several stakeholders expressed interest in human factors evaluation methods like Failure Modes and Effect Analysis (FMEA) or a "Health Care FMEA" that might be deployed to help to develop criteria for levels of risk (e.g., illness, injury, death) that could prompt regulatory action.

Stakeholders suggested that REMS assessments might benefit from leveraging of data sources (e.g., electronic health records, claims data) to conduct assessments. A related recommendation was that FDA assess programs earlier and more frequently throughout a product's life cycle, and apply information gleaned from assessments to modify REMS if needed.

B. Priority Projects

Guided by stakeholder feedback and recommendations, FDA has identified four priority projects, one for each topic area described previously. Each project responds to input the Agency has received regarding significant areas of opportunity for REMS standardization and evaluation efforts.

- Project 1: Providing Benefit-Risk Information to Patients

This project aims to improve the tools used for prescriber-to-patient counseling about REMS drugs. To that end, FDA proposes to conduct research into existing REMS patient counseling tools, other patient counseling initiatives, and counseling literature to identify current tactics and strategies for patient counseling about medication benefits and risk. The Agency intends to seek feedback from a range of stakeholders to identify opportunities to improve the content, format, processes, techniques, and delivery of effective counseling within REMS programs. In addition, FDA intends to develop a public report of findings and counseling processes and tools that could serve as the basis for designing new tools and validating them in demonstration projects.

- Project 2: Prescriber Education

Numerous stakeholders asked FDA to facilitate the provision of health care provider continuing education (CE) for the education and training that is provided in a REMS program. This project will assess whether it is feasible to provide CE certified by the Accreditation Council of Continuing Medical Education, Accreditation Commission for Education in Nursing, and Accreditation Council for Pharmacy Education associated with a specific REMS. FDA will seek to determine at what stage in the drug approval process CE development would best fit (e.g., before or after product approval) and which CE model(s) would be best suited for this type of activity; and provide an analysis of the time and resource burden associated with developing such CE programs.

- Project 3: Pharmacy Systems

FDA proposes to identify an approach for incorporating REMS information into SPL. The project's purpose is to develop a method to share clear and consistent information about the

content of REMS, including REMS documents, requirements, and materials. Doing so will, among other things, facilitate integrating REMS into pharmacy systems and health information technology, including systems for electronic prescribing. SPL will also enable FDA to make structured REMS information available to health care providers and patients, and provide a single conduit of comprehensive information about REMS programs.

- Project 4: Practice Settings

The purpose of this project is to provide a centralized, standardized, reliable, and user-friendly repository of information about REMS, including stakeholders' specific activities and requirements under each REMS program. FDA intends to develop its REMS Web page as a central source of REMS information, which will provide stakeholders in a range of practice settings with a reliable and accessible resource to help them quickly learn about REMS programs, understand and comply with REMS requirements, and compare requirements across REMS to minimize confusion associated with complying with multiple REMS programs.

C. Scope of the Report

This report describes the Agency's findings concerning strategies to standardize REMS where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various health care settings. This report contains project plans to: (1) Increase access to REMS-related information through the use of SPL, (2) enhance the Agency's REMS Web page to better meet the needs of stakeholders, (3) assess the feasibility of using accredited CE courses for prescriber training, and (4) enhance existing tools for prescribers to communicate with patients regarding risks of drugs with REMS, and how those risks should be weighed against the potential benefits of the drug.

III. Electronic Access

Persons with access to the Internet may obtain the document on FDA's Web site at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm350852.htm or http://www.regulations.gov.

IV. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. 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. After consideration of comments, FDA will finalize the report and project plans. The Agency intends to post updates to the project plans on FDA's Web site.

Dated: September 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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