In 2005, FDA issued a guidance for industry on Development and Use of Risk Minimization Action Plans (the RiskMAP guidance), that described how to develop RiskMAPs, select tools to minimize risks, evaluate and monitor RiskMAPs and monitoring tools, and communicate with FDA about RiskMAPs.

In 2009, Guidance for Industry Format and Content Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications (Timetable for submission of assessments, Additional potential elements like Medical Guide, Package insert, Communication Plan for HCPs etc., ETASU)

Drug Administration Safety and Innovation Act (FDASIA), 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)

In 2012, the Food and

Throughout 2013, FDA conducted and/or participated in stakeholder outreach through many mechanisms, including meetings, roundtables, teleconferences, webinars, symposia and seminars

On September 25, 2013, FDA participated with stakeholders in an expert workshop held at the Brookings Institution, "Strengthening Risk Evaluation and Mitigation Strategies (REMS) Through Systematic Analysis, Standardized Design, and Evidence-Based Assessment."





















President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). Authorized FDA to require persons submitting certain applications (applicants) to submit a proposed REMS as part of such application if the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug.

In July 2010, FDA held a public meeting to obtain input on issues associated with the development and implementation of REMS In June 2012, FDA held a public workshop to discuss survey methodologies and instruments that can be used to evaluate patients' and health care providers' knowledge about the risks of drugs marketed with an approved REMS

On July 25-26, 2013, FDA hosted a meeting, "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies," which brought together more than 30 stakeholder organizations and FDA representatives from several offices and divisions within the Center for Drug Evaluation and Research (CDER).

In September 2014 FDA issued REMS Standardization and evaluation report.