What is an FDA Risk Evaluation and Mitigation Strategy?

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The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require manufacturers of drugs and biological products to put in place special programs if the FDA determines that safety measures are needed beyond the professional labeling to ensure that the benefits of products outweigh their risks. The manufacturers then implement FDA-monitored actions to address those risks. The FDA calls each of these a **R**isk **E**valuation and **M**itigation **S**trategy (REMS) [1].

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