

## Paul Dietze, Elizabeth Crompton in Law360: FDA's Risk Evaluation Guidance Brings Clarity, Not Solutions

---

April 29, 2019

---

**PRACTICES** Intellectual Property Litigation, Intellectual Property, Biosimilars

---

This April, the U.S. Food and Drug Administration issued final guidance clarifying how the FDA applies the factors in section 505-1 of the Federal Food, Drug and Cosmetic Act to determine whether a risk evaluation and mitigation strategy is necessary to ensure that the benefits of a drug outweigh its risks.

Section 505-1 of the FD&C Act was created as part of the Food and Drug Administration Amendments Act of 2007. A REMS is a required risk management plan to ensure that the benefits of a drug outweigh its risks.

To approve a drug, the FDA must determine that the drug is safe and effective for its labeled indications under its labeled conditions of use. The REMS guidance notes that “FDA’s determination that a drug is safe, however, does not suggest an absence of risk” and that “a drug is considered safe if it has an appropriate benefit-risk balance.”

A major factor in assessing benefits vs. risks is management of those risks, including both risk assessment and risk minimization. This is an iterative process that involves: “(1) assessing a drug’s benefit-risk balance, (2) developing and implementing tools to minimize the drug’s risks while preserving its benefits, (3) evaluating tool effectiveness and reassessing the benefit-risk balance, and (4) making adjustments, as appropriate, to risk minimization tools to further improve the benefit-risk balance.”

The process continues throughout a drug’s life cycle, as the results of risk assessment inform the sponsor’s decisions regarding risk minimization. ...

To read the full article, click on the PDF linked below.

[Dietze-Crompton-FDA-Risk-Evaluation-Guidance](#)

[First appeared in Law360 on April 26.](#) (Subscription required)