# FDA Issues Draft Guidance on Risk Management and Strategic Plan for Risk Communications

On September 30, the Food and Drug Administration issued two significant documents relating to drug risks. The first provides FDA's thinking on Risk Evaluation and Mitigation Strategies (REMS) for drug products, a new legal authority that took effect in 2008. The second, detailing FDA's Strategic Plan for Risk Communication, outlines more than 70 actions the agency plans to implement to improve its communication of benefit and risk information for drugs and other regulated products.

## Draft Guidance on REMS

The draft guidance, the first substantive and procedural input provided by the agency on the REMS process, provides greater details to pharmaceutical companies faced with the prospect of submitting, implementing, and assessing a REMS. FDA can order a REMS when it determines that risk mitigation measures are required to ensure that a drug's benefits outweigh its risks taking into account the most current safety data available.

Among other things, the draft guidance:

- proposes a format and content to be used in submitting a proposed REMS to FDA;
- addresses the content of the periodic REMS assessments that manufacturers are required to submit; and
- provides an example of a REMS document "template."

The draft guidance envisions the release of additional FDA guidances in the future to address issues such as the imposition of class-wide REMS; agency-industry cooperative efforts to assess the success of REMS programs; and application of REMS to generic drug manufacturers.

## Strategic Plan for Risk Communication

This document outlines more than 70 specific actions FDA plans to take to improve the communication of "meaningful" risk information on regulated products to health care professionals, patients, and consumers. The plan seeks to respond to the criticism leveled against the agency in an Institute of Medicine (IOM) report released in September 2006 that questioned both FDA's track record in approval of drugs subsequently found to have previously undetected risks and the lack of accountability and transparency when releasing information regarding safety concerns.

The Plan identifies three areas – FDA's science base, operational capacity, and policies and procedures – which require action to improve the agency's ability to effectively communicate the benefits and risks of products under its regulatory control. The Plan also identifies specific actions for FDA to implement over the next five years, 14 of which are to be accomplished over the next 12 months.

Among those immediate goals are:

- designing surveys to establish the public's understanding of FDA communication of benefit-risk information;
- creating an internal database of easily accessible risk communication research;
- posting more detailed information regarding Class I and Class II recalls of FDA-regulated products; and
- establishing detailed action plans for internal FDA activities, including internal agency training, to accomplish its communication goals, together with development of a timeline for implementation.

Of particular interest to the pharmaceutical industry is the Plan's discussion of efforts to modernize the FDA's regulatory process in oversight of advertising and promotion of pharmaceuticals, both directed to health care professionals (HCPs) and the public in the form of direct-to-consumer advertising.

## Unanswered Questions

While both FDA releases contain significant information for FDA-regulated products and industries and promise new FDA initiatives, the agency has yet to provide guidance on a number of important questions. Regarding the REMS draft guidance, for example, pharmaceutical manufacturers still have little substantive or procedural guidance on how to assess the success of a REMS plan in addressing risk minimization goals, particularly where a goal of the REMS is to reduce off-label use of a drug.

The FDA Strategic Plan for Risk Communication, notwithstanding the ambitious agenda FDA has set out, is silent with respect to coordination of risk evaluation methods and the resulting communication of risk information at the earliest possible time with drug manufacturers. For example, the Plan states that FDA will assess its ability to share risk information with non-governmental organizations and HCP groups prior to dissemination, but does not acknowledge the critical role of discussing prospective risk communication messaging with the affected manufacturer prior to release.

Ropes & Gray's FDA regulatory lawyers have extensive experience in advising clients on the creation and implementation of REMS as well as appropriate methods of communicating benefit and risk information to HCPs and the public. If you have any questions about either or both of these FDA documents, or any other FDA regulatory matters, please do not hesitate to contact your regular Ropes & Gray attorney.