



FDA Seeks Comments on its Strategic Priorities 2014 – 2018

July 14, 2014

The Food and Drug Administration (FDA) is charged with “protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.” Every four years, the FDA updates its Strategic Priorities document, which outlines the agency's strategic intentions and plans for the years ahead. The agency is currently seeking comments to help it refine its [Strategic Priorities FY 2014-2018](#).

The proposed FY 2014-2018 strategic priorities document is divided into two sections: Cross-Cutting Strategic Priorities and Core Mission Goals and Objectives. The document also identifies five cross-cutting strategic priorities and four core mission goals that will guide efforts to achieve the FDA's public health mission and to fulfill its role in supporting the larger mission and strategic goals of the Department of Health and Human Services (HHS): (1) regulatory science, (2) globalization, (3) safety and quality, (4) smart regulation, and (5) stewardship. The four core mission goals are: (1) enhance oversight of FDA-regulated products, (2) improve and safeguard access to FDA-regulated products to benefit health, (3) promote better informed decisions about the use of FDA-regulated products, and (4) strengthen organizational excellence and accountability.

In 2011, the agency developed a [Strategic Plan for Regulatory Science](#). Regulatory science is defined as “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.” That plan identified eight priority areas of regulatory science where new or enhanced engagement is essential to its mission, including “*Strengthening Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products*.” This priority area addresses the FDA’s need for a science-based approach to developing an effective communication strategy.

The proposed FY 2014-2018 Strategic Priority document includes *Strengthening Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products* as a specific priority (Objective 3.1), and explains that “FDA social scientists, economists, and behavioral scientists build that scientific foundation to inform decision-making about communications and other related effects of FDA actions.”

According to the draft plan, the agency intends to continue to emphasize social and behavioral science over the next four years by:

- Implementing major communications programs based on formative research (helps researchers identify and understand the characteristics – interests, behaviors and needs – of targeted populations that influence their decisions and actions), including an evaluation plan.

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- Exploring and testing interdisciplinary approaches of integrating qualitative and quantitative social science data with traditional and social media analysis and pharmacoepidemiological data to assess communication effectiveness in the use of regulated products.
- Analyzing the intersection of economic and behavioral effects of health safety information about regulated products.
- Increasing the understanding of patients and health care provider perspectives on benefits and risks, including exploring how characteristics of individuals and different medical conditions affect risk tolerance.
- Deepening the understanding of how health care providers regard various types of regulated products, such as biosimilar biologic products.
- Supporting and encouraging research to validate health benefits resulting from consumer dietary changes.

The FDA plans to implement the strategic priorities through a tiered planning framework. The agency's senior leadership will integrate the priorities into the annual budget priority setting and formulation processes, and implementation planning. The [current](#) FDA Strategic Priorities FY 2011-2015 document is available on the agency's website.

Comments to the draft plan may be submitted [electronically](#) or in writing addressed to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

