

MEMORANDUM

From: Joseph A. Levitt
Christine Forgues

Date: February 9, 2018

Re: **FDA's 2018 Strategic Policy Roadmap**

On January 11, 2018, the Food and Drug Administration (FDA or the Agency) issued its 2018 Strategic Policy Roadmap (the Roadmap) in an effort to provide transparency about the FDA's policy undertakings. The Roadmap outlines key priorities that the Agency will pursue in 2018 to advance its public health mission.^{1/} The Roadmap covers all FDA-regulated product areas and includes the following priorities related to food:

- Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease
- Strengthen FDA's scientific workforce and its tools for efficient risk management

FDA notes that there are areas of overlap both between all priorities mentioned as well as with other aspects of work at FDA. Importantly, for food regulation, FDA outlined how it will continue to focus on implementing the new Nutrition Facts Panel and menu labeling regulations and associated guidance, as well as continuing to implement FSMA and the associated field realignment that now has a dedicated cadre of food (and feed) inspectors. Other noteworthy inclusions on the nutrition and labeling side are revisions to the "healthy" claims regulations, updating food standards to promote public health, providing new opportunities to make ingredient information more helpful to consumers, and advancing guidance on dietary sodium reduction. On the food safety side, FDA will continue to build its pathogen database networks and, under FSMA, implement preventive controls rules and pay particular attention to implementing the produce safety rule through increased training and collaboration with the states.

We provide below an overview of FDA's priority areas, and the corresponding goals and action items, most relevant to food policy.

^{1/} See Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap Press Release and Report at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm>.

1. Key Priority: Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease

One key initiative under this priority is FDA's "Nutrition Action Plan." The initiative includes two goals: reducing preventable death and disease caused by poor nutrition by ensuring that consumers have access to accurate, useful information to make healthy food choices, and fostering development of healthier food options.

FDA lists the following action items under its priority and goals:

- Issue practical, substantive guidance to advance implementation of the menu labeling regulations
- Provide guidance for industry to implement the new requirements for updating the Nutrition Facts label
- Launch a new public education campaign to help consumers maximize the public health benefits of the Nutrition Facts label and new menu labeling provisions
- Initiate a new, comprehensive action plan encompassing steps FDA will take to advance policies that better leverage nutrition and diet as ways to reduce morbidity and mortality from disease. Among steps FDA will consider as part of this plan:
 - Revising requirements for certain existing food label claims such as "healthy"
 - Creating a more efficient review system for evaluating health claims on food labels
 - Modernizing certain standards of identity to address current barriers to the development of healthier products while making sure consumers have accurate information about the foods they eat. Among other steps, FDA intends to issue a request for information to identify and help prioritize which potential standards of identity should be modernized based on their public health value
 - Providing new opportunities to make ingredient information more helpful to consumers
 - Advancing guidance on dietary sodium reduction

2. Key Priority: Strengthen FDA's scientific workforce and its tools for efficient risk management

One key initiative under this priority is to "Strengthen Food Safety." The initiative's goal is to strengthen the safety of the foods that Americans eat by continuing to fully implement preventive controls and enhancing collaboration with farmers, food producers, and state and local regulators.

FDA lists the following action items under its priority and goal:

- Advance adoption of preventive controls by food producers with new measures to ensure the feasibility of these methods while strengthening FDA's tools and processes for protecting the public health
- Establish a modern, science-based, efficient framework for FDA's oversight of agricultural water to ensure standards and recognized testing methods are practical and effective
- Ensure proper implementation of FSMA through new education, training, and outreach to farming operations, including by expanding On-Farm Readiness Reviews. To foster better collaboration with state regulators, FDA is also examining and potentially piloting a new approach to how the Agency issues observations made during on-farm inspections
- Take new steps to ensure that farmers, food producers, and state regulators have the training needed to implement the Product Safety and Preventive Controls rules

- Expand FDA's GenomeTrakr network domestically and internationally, building on its freely accessible database of genetic sequence information and metadata from food, environmental and human clinical isolates of bacterial pathogens to improve outbreak detection and to better understand how contamination can occur in order to prevent future outbreaks
- Invest in new research to modernize toxicology testing across food safety and FDA's other regulated product areas

Another key initiative under this priority is "Building a Strong FDA." The initiative's goal is to ensure FDA's ability to bring innovative new products to consumers and use the latest science to improve public health by investing in the scientific and clinical expertise of the Agency's staff and its policies.

FDA lists the following relevant action items under its priority and goal:

- Conduct a comprehensive evaluation of the Agency's hiring practices and procedures and modernize the process for recruiting, retaining, and supporting personnel to strengthen the hiring goals required to meet FDA's evolving needs
- Implement a new realignment of the Agency's field activities with the program areas that FDA oversees to better integrate and coordinate inspection staff and review staff
- Ensure that the Office of the Commissioner is structured and aligned for organizational efficiency and effectiveness: Conduct an assessment of the OC organization and reporting structures
- Modernize FDA's technology landscape to better serve stakeholder needs: Conduct a comprehensive assessment of FDA's IT structure, with the goal of creating a future state that meets the needs of stakeholders in an efficient, effective way

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We will continue to monitor FDA's activities and implementation of priorities outlined in the Roadmap. Please contact us with any questions.