FDA Releases Draft of Foods and Veterinary Medicine Program
Strategic Plan for 2012-2016

On September 30, 2011 the Food and Drug Administration’s (FDA) Foods and Veterinary Medicine Program (FVM) released a draft of its Strategic Plan for 2012 through 2016. FVM is comprised of the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM), and is supported by the Office of Regulatory Affairs. The FVM Strategic Plan covers all activities within the jurisdictions of CFSAN and CVM and outlines one cross cutting goal and seven strategic program goals. Each goal encompasses discrete objectives and is supplemented by key initiatives to help FVM achieve its objectives.

The Strategic Plan states that these goals, objectives and initiatives “reflect[] FDA’s current thinking about the activities that will be key to building a modern system that can meet the challenges posed by the current food safety, nutrition and animal health environments and meet the expectations of FDA stakeholders.” Through the Strategic Plan, FVM recognizes that the public has high expectations of FDA and FDA has tremendous opportunity to affect the public’s health and safety.

The Strategic Plan also highlights, however, many challenges that FDA currently faces. One such challenge is globalization, as it has increased the volume, variety, and complexity of items entering the U.S. food system. FDA is also working to address foodborne illness and diet-related disease, such as diabetes, obesity, heart disease and stroke. Advances in technology and accompanying shifts in consumer expectation are two additional challenges for FDA.

The Strategic Plan is intended to carry out FVM’s program vision and mission. FVM’s vision is to protect consumers and promote the public health by safeguarding America’s food supply and enabling consumers to choose healthy diets. Its mission is to secure high rates of compliance with science-based food safety and labeling standards to 1) protect the safety and security of food for humans and animals, 2) regulate the safety and effectiveness of animal drugs, and 3) ensure that food labels contain useful and reliable information.

FVM has laid out one cross cutting goal and seven other substantive goals to guide its work from 2012 to 2016. These goals are explained in detail below:

Cross Cutting Goal  Improve effectiveness and efficiency across all levels of the FVM Program

The overarching goal of the Strategic Plan is internal in nature. The aim is to improve management of FVM and promote optimal and timely use of resources. Specific objectives that FVM will use to accomplish this goal include developing and implementing an evidence-based resource planning model that will enable FVM to better measure health outcomes. FVM will also develop public health metrics for foods safety, which will allow it to conduct period surveillance and identify the most significant hazards in the food system. Overall, this will help FVM enhance risk-based decision making.
Goal 1
Establish science-based preventive control standards across the farm-to-table continuum

Between 2012 and 2016 FVM will introduce a series of new safety standards and practices to prevent contamination of all food and feed. These standards will be science-based and informed by the latest food safety research. FVM intends these standards to provide clear and current direction to industry on the responsibilities of food system operators with regard to preventive controls. FVM will pay special attention to food handler education, retail food safety, and consumer education. To support the continuous improvement of its preventive controls, FVM will continue to research and evaluate these standards.

Some of the key initiatives that accompany this goal include setting preventive control standards in the areas of food and feed processing facilities, produce safety, safe food transport, and international contamination. FVM also intends to set recordkeeping standards for the administration of drugs to food producing animals.

Goal 2
Achieve high rates of compliance with preventive control standards domestically and internationally

FVM is undertaking a paradigm shift in the way it measures success. Rather than simply tracking activities and outputs, the Strategic Plan announces FVM’s intention to focus on the impact that its activities have on public health, including animal health. To accomplish this, FVM will improve its knowledge of the global supply chain to inform the way FVM personnel conduct inspections. Ultimately, inspectors will make real-time resource allocation decisions by applying a case-by-case evaluation of the risks presented by each facility. FVM hopes to improve collaboration on inspection and compliance efforts.

To accomplish this goal, FVM will employ key initiatives of working with industry to foster state-of-the-art tracing systems in addition to establishing and updating training for Federal, State, local, tribal, and territorial public health officials. Other key initiatives related to this goal include fostering an accredited third-party certification program, creating a voluntary qualified importer program, and working on joint regulatory programs with foreign counterparts. Additionally, FVM plans to utilize its administrative detention authority, suspension of registration authority, and mandatory recall authority as needed.

Goal 3
Strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making

Over the next several years, FVM will continue to recruit and train expert scientists and improve its technological, laboratory and analytic capabilities. This will enable FVM to accomplish its objective of strengthening mission-critical science capabilities. FVM will focus on improving internal and external information sharing and will strive to establish a centralized planning and performance management system.

Key initiatives include communicating research plans and results within FVM and to the public, supported by a new centralized IT infrastructure to share data. FVM will improve communication with food and feed importers to provide rapid notification of test results. It also intends to increase collaboration with foreign regulatory bodies to share risk-based data on firms, farms, and importers.
Goal 4  
Provide accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity

FVM will promote consumer awareness and education on the diet and its impact on health. To improve consumer health information, FVM plans to update nutritional facts labels in light of current nutrition and health information. This may include more prominent calorie declarations and FVM will explore front-of-pack nutrition labeling. Serving size information, daily values, and key nutrient labeling are also likely to be updated. Furthermore, FVM intends to create menu and vending machine labeling regulations. Pet food labeling standards will also be updated and there are plans to implement standards for animal feed ingredients.

Key initiatives include rulemaking on the labeling changes, already described. FVM also plans to publish a final rule defining use of the term “gluten free” in food product labeling. FVM will collaborate with states and localities to ensure high rates of compliance with its new labeling requirements.

Goal 5  
Encourage food product reformulation and safe production of dietary supplements

FVM is committed to reducing sodium content and industrially produced trans fat in the food supply. This includes sodium and trans fats in packaged and restaurant foods. FVM intends to research and analyze the role of sodium in taste, safety and other food attributes in determining how best to reduce sodium content. Additionally, FVM is concerned with the safety of dietary supplements and will continue to carry out the Dietary Supplement Health and Education Act of 1994.

To achieve these goals, FVM will implement key initiatives including conducting modeling to assess sodium intake from salt added to foods. FVM will publish an updated trans fat intake assessment. Also, FVM will advance pre-market oversight of dietary supplements through implementation of the new dietary ingredient guidance.

Goal 6  
Improve detection of and response to foodborne outbreaks and contamination incidents

The Strategic Plan acknowledges that, despite FVM’s emphasis on prevention, contamination and illness outbreaks are a reality of the food system. FVM’s goal is to detect and contain any outbreaks that occur. FVM will focus on improved data collection and adoption of innovative technologies to detect food safety events. This includes enhancing the implementation of the Reportable Food Registry, which is already in place.

Key initiatives related to this goal include operationalizing the Coordinated Outbreak Response and Evaluation (CORE) Network and improving techniques for coordinating with industry during outbreak investigations.

Goal 7  
Advance animal drug safety and effectiveness

FVM will continue to emphasize increased access to safe animal drugs and reduced risk of harm from unsafe animal drugs. This includes reducing the availability of substandard and
illegally marketed animal drugs. FVM will also work to foster the judicious use of medically important antibiotics to reduce antimicrobial resistant strains in food-producing animals.

To achieve this goal, FVM will utilize key initiatives such as ensuring that user fee timeframes are met and enhancing the Adverse Drug Event pharmacovigilance surveillance system. FVM will also develop an enforcement strategy that removes unsafe, ineffective and copycat animal drugs from the market.

The full text of the 2012-2016 Strategic Plan is available at: http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm273269.htm. FVM has stated that it is strongly committed to the central theme of the Strategic Plan, but it welcomes comments and will not hesitate to modify specific elements of the plan accordingly. These comments are invited until November 1, 2011 and can be submitted to FDAFVMStrategicPlan@fda.hhs.gov.

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For more information on the Strategic Plan or for help submitting comments please contact Kathryn Coniglio at coniglio@khlaw.com or Mel Drozen at drozen@khlaw.com.