Food, Dietary Supplement & Cosmetics Regulatory Update
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Top Stories

FDA Calls for New Comments on Revised Proposals for FSMA Rules
Last month, FDA announced several revisions to enhance four proposed rules that address policies on produce safety, foreign supplier verification, and preventive controls for human food and for animal food. First released in 2013, the proposals aim to implement the Food Safety Modernization Act ("FSMA") but are now being revised in response to significant criticism of the original plans by industry. Importantly, the *Federal Register* notices extend the comment period for the four proposals to December 15, 2014, but the agency indicates it will consider only comments related to the new revisions. FDA is expected to issue a consolidated set of final rules based on the original and supplemental proposals.

The modified provisions cover a range of issues. As a general matter, the modified proposed produce safety rule provides for more flexible testing of water quality and revises the definition of covered farms. The new proposed rule for preventive controls for human food would exempt farms that pack or hold food for other farms from facility registration requirements, and it would allow suppliers an option to determine the appropriate verification method to use after a significant hazard is identified.
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Responding to a Changing World, FDA Outlines Five Strategic Priorities for Agency
On September 30, 2014, FDA released a new report, *FDA Strategic Priorities: 2014–2018*,

intended to help the agency navigate rapidly evolving industries and other global changes over the next few years. The report sets forth an integrated framework of five strategic priorities—regulatory science, globalization, safety and quality, smart regulation, and stewardship—and charts four core goals for FDA to pursue through 2018. Commissioner Margaret Hamburg expects the Strategic Priorities to help address "new challenges and transformative developments in global science, technology and trade," which are quickly changing the environment in which FDA works. FDA-regulated products now account for 20 percent of U.S. consumer spending, but such goods are increasingly sourced from abroad and produced through advanced technologies.

Specifically, FDA plans to enhance oversight of regulated products, such as food, by promoting interagency collaboration and improved methods for rapidly detecting and stopping foodborne contaminants. The agency is also focused on increasing access to products that benefit health by making strides in the predictability, consistency, and efficiency of regulatory reviews. In addition, the agency hopes to promote informed decision-making by consumers and to strengthen organizational accountability, for example by modernizing its bioinformatics systems to ensure the most up-to-date data is used for food and feed safety.

President Obama Signs Executive Order on Combating Antibiotic-Resistant Bacteria
On September 18, 2014, President Obama signed an Executive Order and issued a national strategy to spur action within the federal government to address the public health challenge of antibiotic-resistant bacteria. The policies aim to encourage the "judicious use of antibiotics" and slow the emergence of antimicrobial resistance. In particular, the Order urges FDA and USDA to continue working to eliminate the use of certain antibiotics "for growth promotion purposes in food-producing animals." The Order also creates a national task force led by the Secretaries of the Department of Agriculture, Department of Health and Human Services, and Department of Defense, charged with submitting a five-year action plan by February 15, 2015.

Food Facilities Have Through Year-End to Renew Registrations
FDA's Center for Food Safety and Applied Nutrition recently issued a constituent update reminding food facilities to renew their facility registrations during the period October 1, 2014, to December 31, 2014. In 2011, the FSMA amended the food facility registration requirements of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") to provide for a biennial renewal process. Registration generally applies to domestic and foreign food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. For additional information, FDA has a Q&A guidance on the registration requirements.

FDA Launches Food Safety Challenge to Target *Salmonella* Detection
Reaching out to private-sector innovators, FDA recently announced its first Food Safety Challenge to encourage breakthrough ideas for detecting *Salmonella*, the disease-causing organism responsible for nearly 3,000 deaths in the United States every year. Authorized by the America COMPETES Reauthorization Act of 2010, the competition offers a total prize pool of $500,000 to up to five finalists who develop the best concepts for addressing the detection of *Salmonella* in minimally processed fresh produce. Scientists, engineers, entrepreneurs, and others can submit project proposals by November 9, 2014. Other rules are explained on the 2014 Food Safety Challenge website.

Other News
FDA Deputy Commissioners Offer Reflections on 2009 Peanut *Salmonella* Outbreak

FTC and FDA Issue Joint Warning Letters to Firms Marketing Products to Treat Ebola Virus

Senate Passes Bill to Promote Faster Approval of Sunscreens

European Commission Restricts Three Cosmetics Preservatives

Democratic Senators Push for Increased NARMS Funding

Private Researchers, FDA Scrutinizing Potential Health Risks of Tattoo Inks

Regulatory Updates

FDA Offers Revisions to Proposed Rule on Produce Safety
In the September 29, 2014, *Federal Register*, FDA issued amendments to specific provisions of the proposed rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Among the revisions, FDA proposes a water quality standard and more flexible testing, clarifies the definition of "covered farm," revises the process for withdrawing qualified exemptions, and eliminates the previously proposed minimum interval for application of composted manure. ***Comments due December 15, 2014***.

FDA Revises Proposed Foreign Supplier Verification Programs Rule
In the September 29, 2014, *Federal Register*, FDA announced revisions to certain provisions of the proposed rule, issued in July 2013, on foreign supplier verification programs for importers of food for humans and animals. In response to extensive public input, FDA is revising the proposed requirements concerning compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities—all in coordination with revisions concurrently being made to the proposed rule on CGMP and hazard analysis and risk-based preventive controls. ***Comments due December 15, 2014***.

FDA Announces Revisions to CGMP, Hazard Analysis Proposed Rule
In the September 29, 2014, *Federal Register*, FDA is proposing to amend its 2013 proposed rule for CGMP and Hazard Analysis and Risk-Based Preventive Controls for Food for Humans and for Animals. In that 2013 proposed rule, FDA proposed to add CGMP requirements and to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food. ***Comments due December 15, 2014***.

FDA Announces 2014 Food Safety Challenge
In the September 24, 2014, *Federal Register*, FDA announced the 2014 FDA Food Safety Challenge, a prize competition under the America COMPETES Reauthorization Act of 2010 that aims to advance breakthroughs in foodborne pathogen detection, specifically with the goal of accelerating the detection of *Salmonella* in fresh produce. The competition has four phases, with the submission phase September 23, 2014, to November 9, 2014. Winners will be announced March 12, 2015.

USDA's FSIS to Allow for Electronic Import Inspection Application, Certification
In the September 19, 2014, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") issued a final rule amending the meat, poultry, and egg products import regulations to provide for the Public Health Information System ("PHIS") Import Component. Launched on May 29, 2012, the PHIS Import Component provides an electronic alternative to the paper-based import inspection application and the foreign inspection and foreign establishment certificate processes. USDA is also requiring Sanitation Standard Operating Procedures at official import inspection establishments and discontinuing other procedures, such as its practice of conducting imported product reinspection based on a foreign government's guarantee to replace a lost or incorrect foreign inspection certificate. ***The rule is effective November 18, 2014***.

USDA Issues Final Rule on Test Results for Veterinary Biological Products
In the September 18, 2014, *Federal Register*, USDA issued a final rule defining the terms used for reporting test results on veterinary biological products. Licensees and permittees of veterinary biological products must conduct these tests and report the results to the Animal and Plant Health Inspection Service so USDA can determine if the products are eligible for release. The rule removes several obsolete testing standards and clarifies the circumstances under which the results of a prescribed test can be reported as satisfactory,

unsatisfactory, inconclusive, or a "no test." ***The rule is effective October 20, 2014***.

USDA Issues Final Rule on Importation of Mangoes From Jamaica
In the September 18, 2014, *Federal Register*, USDA issued a final rule amending the fruits and vegetables regulations to allow the importation of mangoes from Jamaica into the continental United States. As a condition of entry, the mangoes will be subject to safety systems and measures to mitigate the risks of fruit flies. ***The rule is effective October 20, 2014***.

USDA Accepting Nominations for Advisory Committee on Agriculture Statistics
In the September 18, 2014, *Federal Register*, USDA announced an invitation for nominations to the Advisory Committee on Agriculture Statistics. The Advisory Committee counsels the Secretary of Agriculture on the scope, timing, content, and other matters related to the periodic censuses and surveys of agriculture; prepares recommendations regarding the content of agriculture reports; and presents the views and needs for data of major suppliers and users of agriculture statistics. ***Nominations due October 24, 2014***.

USDA Accepting Nominations for National Advisory Council on Maternal, Infant, and Fetal Nutrition
In the September 26, 2014, *Federal Register*, USDA's Food Nutritional Service ("FNS") is seeking nominations for nine vacancies on the 24-member National Advisory Council on Maternal, Infant, and Fetal Nutrition. The Advisory Council studies the operation of the Special Supplemental Nutrition Program for Women, Infants, and Children, and related programs such as the Commodity Supplemental Food Program. ***Nominations due October 27, 2014***.

USDA Determines Certain Herbicide-Resistant Corn, Soybean Not Subject to GMO Regulations
In the September 22, 2014, *Federal Register*, USDA announced its determination that three varieties of herbicide-resistant corn and soybeans produced by a citizen petitioner are no longer considered regulated articles under USDA regulations governing the introduction of certain genetically modified organisms ("GMOs"). USDA made the determination based on evaluation of information submitted by the petitioner, public comments, and other publicly available scientific data.

FDA Information Collection Activities

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections:
Veterinary Feed Directive (*comments due November 24, 2014*)

FDA Announced the Following Information Collections Have Been Submitted to OMB:
Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle (*comments due to OMB October 27, 2014*)

FDA Announced the Following Information Collections Have Been Approved by OMB:
Threshold of Regulation for Substances Used in Food-Contact Articles

Voluntary Cosmetic Registration Program

USDA Information Collection Activities

USDA Announced the Opportunity to Comment on the Following Proposed Information Collections:
Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Forms: FNS-698, FNS-699 and FNS-700; The Integrity Profile (TIP) (*comments due November 17, 2014*)

Organic Certifiers Survey (*comments due November 24, 2014*)

United States Warehouse Act (*comments due November 28, 2014*)

USDA Announced the Opportunity to Comment on the Following Request for Revisions to and/or Extensions of Approval of Information Collections:
Qualitative Feedback on Agency Service Delivery (*comments due November 17, 2014*)

Trichinae Certification Program (*comments due November 17, 2014*)

Salmonella Initiative Program (*comments due November 18, 2014*)

USDA Announced the Following Information Collections Have Been Submitted to OMB:
National Veterinary Services Laboratories Request Forms (*comments due to OMB October 17, 2014*)

Importation of Tomatoes from Spain, Chile, France, Morocco, and Western Sahara (*comments due to OMB October 20, 2014*)

Food Safety Education Campaign Post-Wave Tracking Survey (*comments due to OMB October 23, 2014*)

Report and Recordkeeping Requirements (*comments due to OMB October 23, 2014*)

USDA Program Discrimination Complaint Form (*comments due to OMB October 23, 2014*)

Volunteer Programs (*comments due to OMB October 24, 2014*)

WIC Farmers' Market Nutrition Program Forms and Regulations (*comments due to OMB November 26, 2014*)

Long-Term Contracting (*comments due to OMB October 29, 2014*)

Other USDA Announcements
USDA Extends Comment Period on Study of U.S. Standard of Identity for Honey (*comments due October 21, 2014*)

USDA Affirms Interim Rule as Final Rule for Amendments to National Sheep Industry Improvement Center

USDA Releases Environmental Assessment on Proposed Release of *Diaphorencyrtus aligarhensis* for the Biological Control of the Asian Citrus Psyllid, *Diaphorina citri* in the Contiguous United States

USDA's FSIS Announces Changes in Accredited Laboratory Fees

USDA Issues Rule Implementing Agriculture Risk Coverage and Price Loss Coverage Programs

USDA Announces Renewed Charter of General Conference Committee of the National Poultry Improvement Plan

Upcoming Meetings, Workshops, and Conferences

Listening Session on Rural Community College Coordinated Strategy, **October 9, 2014**, Washington, D.C.

Meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses, **October 28, 2014**, College Park, MD.

Meeting of the Organic Standards Board, **October 28–30, 2014**, Louisville, KY.

FDA Risk Communications Advisory Committee Meeting, **November 3–4, 2014**, in Washington, D.C.

FDA Food Advisory Committee Meeting, **December 16–17, 2014**, in Washington, D.C.

Enforcement Updates

Recent Product Recalls
Recent food recalls involved microbial contaminations, undeclared allergens, and inspection and storage temperature failures.

Companies continue to recall food products that contain undeclared allergens. According to FDA's website, packages of milk chocolate candies were recalled after some packages were found containing undeclared peanut butter. A brand of bread crumbs was called back for not properly listing wheat, whey, and soy ingredients, and another manufacturer recalled several batches of lobster bisque that contained undeclared shrimp.

A seafood importer recalled packages of dried fish following a routine sanitary inspection by a state agriculture department that revealed a high risk of botulism contamination. In addition, carob powder products and certain pet foods were recalled because of potential *Salmonella* contamination.

USDA posted information about recalled beef products due to potential *E. coli* contamination and recalled chicken strips for *Listeria* concerns. There were also recalls of beef corndogs for improper storage temperatures and certain beef jerky products for being shipped without inspection.

For a complete list of product recalls, click here for FDA-regulated products, and here for USDA-regulated products.

Recent Warning Letters
FDA recently warned a baked goods producer for myriad misbranding violations related to false or misleading claims on the packaging, failure to declare allergens, and failure to list all ingredients in the ingredient statement. Notably, FDA issued a rare warning on the term "natural," which the agency has declined to define, but instructed the baked goods manufacturer that its "all-natural" claim was misleading because the product contained a synthetic ingredient. FDA also cited the manufacturer for failing to make required reports to the Reportable Food Registry on two occasions where customers complained about allergic reactions to a product. A frozen food processor was cited following an inspection that revealed *Listeria* contamination and multiple labeling violations related to the ingredient statement and failure to declare an allergen. Two other companies were issued warning letters for rodent and insect activity.

In a significant move, FDA and FTC jointly issued warning letters to three companies for marketing essential oils and other products for the purposes of preventing or treating the Ebola virus. Such claims make the products unapproved drugs, sold in violation of the FD&C Act, and also lack adequate substantiation, in violation of the fair advertising provisions of the Federal Trade Commission Act. The warning letters note these products were advertised on various social media sites, including Pinterest.

FDA also posted warning letters to two dietary supplement manufacturers for illegally marketing, as dietary supplements, products that contain active pharmaceutical ingredients. The companies were also cited for making disease claims on dietary supplement products, and one of the firms was additionally cited for failing to comply with CGMP requirements.

Four seafood processing facilities were cited for hazard analysis and critical control points, or HACCP, violations, including failures to conduct risk analyses for each product and to

implement affirmative steps. FDA also issued warning letters to three cattle farms and a feeder for illegal drug residue found in cows sold for slaughter.

Click here for FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).

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The revised preventive controls for animal food would make similar changes and apply a more flexible approach to certain Current Good Manufacturing Practice ("CGMP") requirements for human food producers who supply by-products for animal food manufacturing. Finally, the revisions to the proposed rule concerning foreign supplier verification programs would establish a more comprehensive evaluation of hazard controls, including new factors that importers must consider when evaluating food coming into the country. For more information, see the "Regulatory Updates" section in this issue.

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