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Issue 18 | November 2014

JONES DAY

FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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FDA Announces New Director for CFSAN
On November 10, 2014, FDA announced that Susan Mayne, Ph.D., an expert in nutrition, toxicology, and epidemiology, will become director of the Center for Food Safety and Applied Nutrition ("CFSAN") when Michael Landa resigns in January 2015. In its announcement, FDA indicated that CFSAN is "transforming the food safety system and taking new steps to address chronic disease and obesity," noting that Mayne's experience will provide strong support for these initiatives. Mayne is currently a professor at the Yale School of Public Health and associate director of the Yale Cancer Center. She will take over the CFSAN position from Landa, who has led the Center since 2010.

Incoming GOP Senate Will Likely Encourage Less FDA Regulation
The incoming Republican majority resulting from last week's midterm elections will likely try to challenge FDA on several fronts, seeking to ease regulatory burdens—or prevent the creation of additional burdens—for the food and dietary supplement industries. Some in the food industry are hopeful the Republican control in the Senate will boost the chances of passing a bill giving FDA sole authority to require mandatory GMO labeling. If the bill passes, it would override the costly, state-by-state GMO labeling battles.

Some analysts have predicted that a Republican-controlled Congress will make it hard for Democrats to push through any efforts to amend the Dietary Supplement Health and Education Act. However, pundits expect the new CFSAN director to be more aggressive with the food industry. Similarly, consumer groups show few signs of relenting in their efforts to hold industry or FDA more accountable for what goes into food.

FDA Considers Expanding Food Ingredient Safety Testing Guidance to New Dietary Ingredients and Cosmetics
FDA is dusting off the Red Book to update the guidance document and consider whether it might be useful for regulating more than just food and color additive safety. Formally known as *Toxicological Principles for the Safety Assessment of Food Ingredients*, FDA's Red Book was originally published in the 1980s as guidance to industry and other stakeholders regarding the information CFSAN used to evaluate the safety of food and color additives during the premarket review process. Although the Red Book has often languished between updates, in a public meeting announcement published last week, FDA announced it would be revising the document and expressed interest in expanding the scope of the guidance to cover chemical safety assessments for new dietary ingredients, food contact substances, and cosmetics, among others. FDA will hold a public meeting on December 9, 2014, in College Park, Maryland, to collect public input, although ***interested parties may submit comments through February 9, 2015***.

GMO Labeling Defeated in Oregon, Colorado; Maui Passes GMO Crop Ban
In last week's midterm elections, residents in both Oregon and Colorado voted against ballot initiatives that would have required labeling foods made with genetically modified organisms ("GMOs"). In Oregon, the measure was narrowly defeated; the Colorado measure was rejected by a large margin. Several biotech companies poured millions into "vote no" campaigns in both states, arguing the patchwork approach to varying laws across states would increase food costs. Interestingly, voters in Maui County, Hawaii, narrowly approved an initiative temporarily banning genetically engineered crops until certain environmental and public health studies are conducted.

Environmental, Public Health Groups Sue FDA Over Approval of Controversial Animal Feed Additive
Last Thursday, advocacy groups including the Center for Food Safety ("CFS"), the Center for Biological Diversity, and Sierra Club sued FDA over the Agency's approval of ractopamine-based drugs used to increase the growth of livestock. The drugs, first approved by FDA in 1999, are widely used in hogs. The groups are challenging FDA's approval of the drugs, arguing that the Agency neglected to study the necessary environmental analysis and that the drugs are leaching into waterways, contaminating wildlife and water supplies, and are toxic to various species. The advocacy groups also argue that the drugs are associated with high stress levels in animals, lameness, hyperactivity, broken limbs, hoof lesions, and death. The European Union, China, and Russia have banned U.S. pork products made from pigs fed ractopamine drugs. Last year, CFS and the Animal Legal Defense Fund challenged FDA's withholding of records related to the ractopamine approval.

Other News
FDA and Asia-Pacific Colleagues Focus on Food Safety

FDA Initiates Process to Tackle Weight Loss Claims by Dietary Supplement Companies

Berkeley, California, Enacts Country's First Soda Tax

CSPI Requests Release of FDA Study About Illegal Drug Residues in Milk

FDA Rejects Calls to Ban Aspartame

FDA to Send More Food Inspectors to China

Group Petitions FDA to Weigh In on "100% Grape Juice" Heart-Health Ad Scheme

Regulatory Updates

USDA Announces Determination of Nonregulated Status of Potato Genetically Engineered for Low Acrylamide Potential and Reduced Black Spot Bruise
In the November 10, 2014, *Federal Register*, USDA announced its determination that it no longer considers certain potatoes designated as Innate™ Potato, which have been genetically engineered for low acrylamide potential and reduced black spot bruise, as subject to GMO regulations. Acrylamide is a human neurotoxicant and potential carcinogen that may form in potatoes and other starchy foods under certain cooking conditions. In response to a citizen petition, USDA decided such products are not subject to regulations governing the market introduction of certain GMOs. The determination is effective immediately.

USDA Announces Filing of Citizen Petition for Nonregulated Status of Late Blight-Resistant, Genetically Engineered Potato
In a separate notice in the November 10, 2014, *Federal Register*, USDA announced the filing of a citizen petition requesting a determination of nonregulated status for certain Innate™ Potato designated as Russet Burbank event W8, which has been genetically engineered for late blight resistance, low acrylamide potential, reduced black spot bruising, and lowered reducing sugars. ***Comments due January 9, 2015***.

USDA Adopts Final Rule on Testing for Brucella "Class Free" Status in Cattle
In the November 10, 2014, *Federal Register*, USDA announced it is adopting as a final rule, with changes, an interim rule amending the brucellosis regulations to reduce the amount of testing required for states to maintain "Class Free" status with respect to cattle and domestic bison. "Class Free" means the state has been determined to have no *Brucella abortus* in wildlife, which requires testing livestock for the bacteria. As amended, the final rule sets the age at which cattle and domestic bison are included in herd blood tests and allows certain states the option of either conducting brucellosis ring tests and participating in the slaughter surveillance program or developing a reasonable alternative surveillance plan. ***The final rule is effective December 10, 2014***.

FDA Announces Filing of Food Additive Petition for Use of *Salmonella*-Bacteriophage Preparation in Dry Pet Food
In the November 6, 2014, *Federal Register*, FDA announced the filing of a citizen petition proposing to amend the food additive regulations to provide for the safe use of a *Salmonella*-specific bacteriophage preparation as a food additive, specifically as an antimicrobial processing aid to reduce such bacteria in the production of dry dog and cat pet food. ***Comments due December 8, 2014***.

USDA Issues Interim Rule on Conservation Stewardship Program
In the November 5, 2014, *Federal Register*, USDA issued an interim rule amending the existing Natural Resources Conservation Service regulation for the Conservation Stewardship Program, a voluntary program providing incentives to agricultural participants to achieve certain conservation objectives. The interim rule incorporates programmatic changes authorized by the Agricultural Act of 2014. Although subject to comments, the interim rule is effective November 5, 2014. ***Comments due January 5, 2015***.

USDA Extends Comment Period for Final Rule on Dairy Protection, Donation Programs
In the October 30, 2014, *Federal Register*, USDA issued a notice extending the comment period by 45 days for the final rule implementing regulations for the Margin Protection Program for Dairy and the Dairy Product Donation Program as authorized in subtitle D of the Agricultural Act of 2014. The Commodity Credit Corporation and Farm Service Agency published the final rule on August 29, 2014. ***Comments now due December 15, 2014***.

USDA Reopens Comment Period for Proposed Rule on Importation of Beef from Northern Argentina
In the October 31, 2014, *Federal Register*, USDA issued a notice reopening the comment period for a proposed rule to allow the importation of fresh (chilled or frozen) beef from a certain region of Argentina under certain conditions. USDA originally announced the proposed rule on August, 29, 2014. ***Comments now due December 29, 2014***.

USDA Issues Notice of Inquiry Regarding Beef Promotion, Research Order
In the November 10, 2014, *Federal Register*, USDA issued a notice of inquiry and request for public comments to inform development of a beef promotion, research, and information order under the Commodity Promotion, Research, and Consumer Information Act of 1996. Interested parties may recommend what information should be included in an industry-funded promotion, research, and information program for beef and beef products. ***Comments due December 10, 2014***.

USDA Orders Referendum on Marketing Order for Onions Produced in South Texas
In the October 29, 2014, *Federal Register*, USDA ordered a referendum to be conducted among eligible producers of onions grown in South Texas to determine whether they favor continuance of the marketing order regulating the handling of onions produced in the production area. USDA conducted a similar referendum in May 2014 but is conducting another referendum to ensure all eligible producers have the opportunity to vote on the federal marketing order.

Other USDA Announcements
- Reestablishment of the Charter of the Advisory Committee on Minority Farmers for Two-Year Term
- Revision of Marketing Order Regulating the Handling of Spearmint Oil Produced in the Far West
- Notice of Proposed Changes to Section I of the Iowa, Minnesota, North Dakota, and South Dakota State Technical Guides Regarding Wetland Determinations
- Results of Mango Promotion, Research, and Information Order Review
- Notice of Comment on Processed Raspberry Promotion, Research, and Information Order; Late Payment and Interest Charges on Past Due Assessments
- Modification of Container Requirements for Irish Potatoes Grown in Certain Designated Counties in Idaho and Malheur County, Oregon
- Clarification of Grade Requirements for Avocados Grown in South Florida and Imported Avocados

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections
- Substantiation for Dietary Supplement Claims Made Under the Federal FD&C Act
- Extralabel Drug Use in Animals
- Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

FDA Announced the Following Information Collections Have Been Submitted to OMB
- Correction: Notification and Recordkeeping Requirements for Exports
- Application for Participation in the Food and Drug Administration Commissioner's Fellowship Program
- Testing Communications on Food and Drug Administration-Regulated Products Used in Animals
- Food Safety Survey
- Correction: Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

USDA Announced the Opportunity to Comment on the Following Proposed Information Collections
- Quarterly Colony Loss Survey and the Annual Colony Loss Survey
- Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery
- National Institute of Food and Agriculture's Information Collection of Letters of Intent

USDA Announced the Opportunity to Comment on the Following Approved, Revised, and/or Extended Information Collections
- Entry of Specialty Sugars into the United States
- Shell Egg Surveillance Portion of the Egg Inspection Regulations
- Form AD-761, USDA Patent License Application for Government Invention
- Acreage and Crop Reporting Streamlining Initiative

USDA Announced the Following Information Collections Have Been Submitted to OMB
- Virus-Serum-Toxin Act and Regulations
- SNAP-Ed Connection Recipe Submission and Review Forms

Upcoming Meetings, Workshops, and Conferences

Meeting of the National Advisory Committee on Microbiological Criteria for Foods, **November 17, 2014**, in Washington, D.C.

Science Board to FDA, **November 19–20, 2014**, in Silver Spring, MD.

Meeting of USDA's Plant Variety Protection Board, **December 8–9, 2014**, in Chicago, IL.

Meeting on Updates to Redbook, **December 9, 2014**, in College Park, MD.

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

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