Top Stories

FDA Offers Plain-Language Advice on "Gluten-Free" Labeling Requirements
In a follow-up to an August 2013 final rule on voluntary "gluten-free" labeling, FDA issued a small entity compliance guide with questions and answers to help firms comply with the new requirements. The new federal definition standardizes the meaning of "gluten-free" claims across the food industry. In order to use the term "gluten-free" on its label, a food must meet all of the requirements of the definition, including that the food must contain less than 20 parts per million of gluten. The rule also requires foods with the claims "no gluten," "free of gluten," and "without gluten" to meet the definition for "gluten-free." Beginning August 5, 2014, all FDA-regulated foods must comply with the new rule.

FDA Strategy to Reduce Food Animal Antibiotic Use Achieves Full Participation
On June 30, 2014, FDA announced that its strategy to voluntarily reduce animal antibiotic use has the full participation of the 26 companies with operations affected by the policy. The strategy is part of FDA's three-year plan to stop certain food production uses of antibiotics in animals. The plan includes ending the use of antibiotics for growth promotion and requiring veterinary supervision for use of the antibiotics in food animals.

Milk Producers Ask for Exemption from FSMA Intentional Adulteration Rule
Two milk producer associations submitted comments on USDA's proposed rule on intentional adulteration, which requires domestic and foreign food facilities to guard against threats to the food supply posed by terrorism. The milk producers are asking that dairy farms be exempted from the rule or, alternatively, for USDA to require additional safeguards only when a credible threat is identified. The Food Safety Modernization Act ("FSMA") requires USDA to issue the final rule by May 31, 2016.

New York Court of Appeals Refuses to Reinstate Ban on Large Sodas
On June 26, 2014, New York's high court ruled that New York City's health department exceeded its authority when it banned the sale of sugary drinks larger than 16 ounces. The controversial anti-obesity

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Resources

- *Food, Dietary Supplement & Cosmetics Regulatory Update* Printable Version
- Jones Day's FDA Regulatory & Compliance Counseling Practice
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

measure had strong support from former Mayor Bloomberg but was reviled by many restaurants, theaters, and the beverage industry.

Juice Trade Group Petitions FDA to Establish Minimum Strength for Coconut Water
In a Citizen Petition dated July 2, 2014, a trade group representing juice product manufacturers asked FDA to establish a minimum Brix level of 3.9 for coconut water, a fruit juice under FDA regulations. Currently, FDA and USDA have no regulations or guidelines pertaining to coconut water, but the Codex Alimentarius Commission has established a minimum Brix level of 5.0. The trade group submitted data based on juice from coconuts grown in the top-producing regions as evidence for their proposed standard.

Other News
USDA Deputy Secretary Travels to China for High-Level Strategic and Economic Dialogue

Congresswomen De Lauro and Slaughter Introduce Food Pathogen Bill

California Repeals Glove Rule for Food Handlers

CDC Says Antibiotic Resistance in Foodborne Germs is Ongoing Threat

Regulatory Updates

FDA Issues Four Nanotechnology Guidance Documents
On June 27, 2014, FDA announced the availability of four guidance documents—three final and one draft—relating to nanotechnology:

The first guidance, Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives, outlines the factors industry should consider when determining whether changes in manufacturing processes of a marketed food affect the identity, safety, or regulatory status of the food substance. Such changes include the intentional reduction in particle size to the nanoscale.
- read more below

FDA Issues Guidance for Gluten-Free Labeling of Foods
In the June 26, 2014 *Federal Register*, FDA announced the availability of Gluten-Free Labeling of Foods—Small Entity Compliance Guide, a plain-language restatement of the final rule published in the August 5, 2013 *Federal Register*, and ***effective on August 5, 2014***.

USDA Reopens Comment Period for Amendments to Inspection & Quarantine User Fees
In the July 1, 2014 *Federal Register*, USDA announced it was reopening the comment period for its proposed rule amending the user fee regulations to add new fee categories and adjust current fees charged for certain agricultural quarantine and inspection services. ***Comments due July 24, 2014***.

USDA Issues Final Aflatoxin Testing Rule for Pistachios
In the July 3, 2014 *Federal Register*, USDA's Agricultural Marketing Service issued a final rule revising the aflatoxin sampling regulations currently prescribed under the California, Arizona, and New Mexico pistachio marketing order to allow for mechanical samplers. ***Effective August 4, 2014***.

USDA Issues Final Rule on Spearmint Oil
In the July 3, 2014 *Federal Register*, USDA's Agricultural Marketing Service issued a final rule revising the procedure currently prescribed for issuing additional allotments for spearmint oil to new and existing producers under the Far West spearmint oil marketing order, reducing the number of new producers issued allotments each year. ***Effective July 7, 2014***.

USDA Finalizes Interim Rule on Oranges and Grapefruit Grown in Lower Rio Grande
In the July 3, 2014 *Federal Register*, USDA's Agricultural Marketing Service ("AMS") adopted as final, without change, an interim rule relaxing the minimum size and grade requirements for grapefruit. AMS relaxed the size and grade requirements in response to market demand for grapefruits. ***Effective July 7, 2014***.

CVM Amends Animal Drug Rules to Reflect Withdrawal and Approvals
In the July 2, 2014 *Federal Register*, FDA's Center for Veterinary Medicine ("CVM") issued several notices related to approval actions and a withdrawal. First, FDA announced that at the sponsor's request, the Agency had withdrawn certain parts of a new animal drug application approval with respect to the procaine penicillin component for growth promotion indications in swine and amended the animal drug regulations to reflect the withdrawal. Also on July 2, 2014, FDA published technical amendments to the animal drug regulations to reflect approval actions for new animal drug applications and abbreviated new animal drug applications during April and May 2014 and removed an obsolete drug from the regulations.

FDA INFORMATION COLLECTION ACTIVITIES

FDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Exports: Notification and Recordkeeping Requirements (***comments due September 2, 2014***)

FDA Announces the Following Information Collections Have Been Submitted to OMB
Cosmetic Labeling Regulations (***comments due to OMB July 25, 2014***)

Recordkeeping and Records Access Requirements for Food Facilities (***comments due to OMB July 28, 2014***)

Antiparasitic Resistance Survey (***comments due to OMB August 4, 2014***)

FDA Announces that OMB Has Approved Information Collections for the Following
Food Labeling Regulations

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Importer's Entry Notice

USDA INFORMATION COLLECTION ACTIVITIES

USDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Importation of Used Farm Equipment from Regions Affected with Foot-and-Mouth Disease (***comments due September 2, 2014***)

National Poultry Improvement Plan (***comments due September 5, 2014***)

USDA Announces the Following Information Collections Have Been Submitted to OMB
Emergency Conservation Program and Biomass Crop Assistance Program (***comments due to OMB July 28, 2014***)

Child Nutrition Database (***comments due to OMB July 28, 2014***)

Worksheet for SCIMS Record Change (***comments due to OMB July 31, 2014***)

USDA Race, Ethnicity, and Gender Data (***comments due to OMB July 31, 2014***)

USDA Web Based Supply Chain Management System (***comments due to OMB July 31, 2014***)

Importation of Hass Avocado from Michoacán Mexico (***comments due to OMB July 31, 2014***)

South American Cactus Moth Quarantine (***comments due to OMB July 31, 2014***)

Notice of Intent to Grant Exclusive License for Primocaine Management Method and Apparatus (***comments due to OMB July 31, 2014***)

USDA Announces that OMB Has Approved Information Collections for the Following National School Lunch Program: Independent Review of Applications Required by the Healthy, Hunger-Free Kids Act of 2010.

Upcoming Meetings, Workshops, and Conferences

General Conference Committee of the National Poultry Improvement Plan ("NPIP") and the NPIP's 42nd Biennial Conference, **July 10–12, 2014**, in Charlotte, NC.

National Advisory Council on Maternal, Infant, and Fetal Nutrition, **July 15–17, 2014**, in Arlington, VA.

2015 Dietary Guidelines Advisory Committee, **July 17–18, 2014**, via webcast.

International Association for Food Protection Annual Meeting, **August 3–6, 2014**, in Indianapolis, IN.

Enforcement Updates

Recent Product Recalls
Recent FDA recalls involved ingredient and processing issues as well as potential bacterial contamination. Some lots of ice cream were recalled due to mismatched packaging that did not identify the presence of peanuts. Chia and flaxseed were recalled for potential *Salmonella* contamination, and a variety of sauces made by one firm were recalled for improper processing that may have allowed the growth of *Clostridium botulinum* in the products. One cheese product was recalled for levels of preservative that might result in premature spoilage. A dietary supplement firm also withdrew its products from the market because they may contain an undeclared pharmaceutical drug. Birdfeed was also recalled for excessive sodium.

Only four USDA recalls were issued since the last *Update*. Two meat producers recalled products for possible foreign matter contamination. Another producer recalled its chicken products due to possible *Salmonella* contamination. Most recently, a chicken product manufacturer recalled its products because it did not utilize a fully implemented "ready-to-eat" HACCP plan.

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

Recent Warning Letters
FDA continues to post warning letters to dairy operators notifying them that tissue samples of animals sold for food tested positive for unapproved drug residues. Two such letters were posted in the last two weeks. Dietary supplements were another focus of recently posted warning letters. One dietary supplement manufacturing and juice processing facility was warned for a variety of CGMP violations relating to a lack of written procedures and recordkeeping. A dietary supplement distributor received a warning letter for similar CGMP violations as well as misbranding and promoting unapproved new drugs.

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

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The second guidance, Guidance for Industry: Considering Whether a Food and Drug Administration-Regulated Product Involves the Application of Nanotechnology, identifies particle dimensions and dimension-dependent properties or phenomena as two points to consider as initial screening tools.

The third guidance, Guidance for Industry: Safety of Nanomaterials in Cosmetic Products, represents FDA's current thinking on the safety assessment of nanomaterials in cosmetic products. The guidance is intended to help industry identify potential safety issues and develop a framework for evaluating them.

The fourth guidance, Draft Guidance for Industry: Use of Nanomaterials in Food for Animals, applies to food ingredients that are intended for use in food for animals and either: (i) consist entirely of nanomaterials; (ii) contain nanomaterials as a component; or (iii) otherwise involve the application of nanotechnology. It is intended to assist industry in identifying potential issues related to safety or regulatory status of food for animals containing nanomaterials or otherwise involving the application of nanotechnology. Comments on the nanomaterials in cosmetic products draft guidance are due September 10, 2014.