Top Stories

Supreme Court Rules POM Can Sue Coca-Cola for Misleading Advertising
On June 12, the U.S. Supreme Court unanimously reversed the Ninth Circuit, holding that POM Wonderful LLC's false advertising claim against the Coca-Cola Company for misleading advertising was not barred. POM challenged Coca-Cola's labeling for its "Pomegranate-blueberry blended juice," which contained more than 99 percent apple and grape juices. Coca-Cola responded that the Nutrition Labeling and Education Act of 1990 and implementing regulations, with which the labeling fully complied, override the Lanham Act, the federal false advertising law. The Ninth Circuit agreed with Coca-Cola, ruling that the more specific regulations governing food labels precluded this sort of false advertising claim. The Supreme Court disagreed, holding that the Lanham Act and the food labeling regulations coexist because there is no explicit restriction "in either statute [that] discloses a purpose to bar unfair competition claims like POM's." The opinion, authored by Justice Kennedy, also unanimously rejected the federal government's amicus argument that there should be a safe harbor for label statements that are specifically authorized by FDA regulations. Although the Court did not decide whether the label was actually misleading, the Court expressed concern that consumers in general do not receive adequate protection from false advertising. The Court also stated that competitors are better situated than government agencies to call attention to the kinds of deceptive marketing practices alleged in this case. Coca-Cola says it will continue to fight POM's accusation as the case goes to trial.

Burwell Confirmed as HHS Secretary
On June 5, the Senate voted 78–17 to approve Sylvia Mathews Burwell as the next Secretary of Health and Human Services. Burwell, who previously served as the White House budget director, will succeed Kathleen Sebelius as head of the government agency charged with implementing the Affordable Care Act. After the Senate approved her nomination, President Obama credited Burwell's proven management skills and wealth of bipartisan relationships for the strong vote in her favor.

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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

FDA Publishes Compliance Policy Guide Regarding Food Facility Registration
On June 3, FDA issued a revised *Compliance Policy Guide Regarding Food Facility Registration for Human and Animal Food*, which provides guidance for FDA staff on food facility registration requirements, as updated by the Food Safety Modernization Act ("FSMA"). FSMA amended the food facility registration requirements initially established by the Bioterrorism Act of 2002 to require additional registration information, biennial renewal, and assurance that FDA will be permitted to inspect the facility at certain times. FSMA also authorizes FDA to suspend registrations if FDA determines a food facility manufactured, processed, or otherwise handled a food with a reasonable probability of causing harm, and the facility was the cause of the reasonable probability or had reason to know about it. The publication largely reiterates FDA's *Guidance for Industry: What You Need to Know About Registration of Food Facilities*, which lays out FDA's authority to inspect a facility or suspend a facility's registration.

FDA to Hold Public Meeting on Proposed Food Labeling Rules
In the May 29 *Federal Register*, FDA announced a public meeting to discuss two proposed rules aimed at updating nutrition information and serving size requirements on the nutrition facts labels to provide consumers with information used to maintain healthy dietary practices. The meeting will be held on June 26 from 8:30 a.m. to 5 p.m. in Washington, DC. FDA encourages all persons who wish to attend the meeting to register in advance. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. ***Comments on both rules due August 1.***

FDA FY2015 Budget Increased by House Appropriations Committee
On May 29, the U.S. House of Representatives Committee on Appropriations voted 31–18 to increase FDA's 2015 fiscal year budget by nearly $2.6 billion. Food safety activities in particular received an increase of $25 million. USDA's Food Safety and Inspection Service's budget remained the same, around $1 billion.

Latest FDA and USDA Regulatory Agendas Push Several Rules to Fall 2014
On June 2, the White House published its *Current Regulatory Plan and Unified Agenda of Regulatory and Deregulatory Actions* reporting on regulatory priorities for spring 2014. According to the *Agenda*, several key regulations that were expected this spring and summer will not be issued until later this year. For example, actions on adding nutrition labeling to restaurant menus and food in vending machines were supposed to be finalized in February, but now these final rules will issue in June. Similarly, the Modernization of Poultry Slaughter Inspection rule will not be finalized until July, even though it had previously been slated for finalization in April. The final rule on labeling mechanically tenderized beef products will issue in September instead of June. Other regulatory items that are behind schedule include a proposed rule for updating pet food nutrition fact labels, as well as a proposed rule requiring firms to report antimicrobial active ingredients in food-producing animals.

FDA Launches openFDA Providing Easy Access to Valuable Data
On June 2, FDA launched openFDA, a new initiative designed to make it easier for web developers, researchers, and the public to access large, important public health datasets collected by the agency. OpenFDA will make publicly available data accessible in a structured, computer-readable format. It provides a "search-based" application programming interface—the set of requirements that govern how one software application can talk to another—that allows users to find both structured and unstructured content online.

FDA Announces Read the Label Youth Outreach Campaign
On June 3, FDA announced its outreach campaign to teach young people (ages 9–13) to use the Nutrition Facts Label to make healthy food choices. *Read the Label* is the next generation of the FDA's *Spot the Block* campaign for "tweens." The new component features a guide and activities for afterschool and summer program leaders to help kids understand the Nutrition Facts Label on food packages. The comprehensive campaign also includes a wide assortment of downloadable, ready-to-use materials for community educators, families, and adolescents.

Iowa Egg Producer to Pay $6.8 Million Fine for Crimes Related to Tainted Eggs
Two owners of an Iowa egg production facility will pay $6.8 million in fines as part of their plea agreement after pleading guilty to charges of bribery and introducing adulterated and misbranded food into interstate commerce. An employee admitted that he bribed at least one USDA official to allow for the sale of eggs that had been "red tagged" for failing to meet USDA standards. The release of the

tainted eggs resulted in a *Salmonella* outbreak that affected tens of thousands of people and forced the recall of 550 million eggs.

USDA Announces $26.2 Million to Combat Viruses Affecting Pork Producers
On June 5, in response to the significant impact that porcine epidemic diarrhea virus and porcine deltacoronavirus are having on U.S. pork producers, USDA announced $26.2 million in new funding to combat these diseases. Additionally, USDA issued a Federal Order requiring the reporting of new detections of these viruses to its Animal and Plant Health Inspection Service or state animal health officials.

FDA and EPA Update Advice on Fish Consumption and Mercury
The FDA and EPA are revising their joint fish consumption Advice and Questions & Answers to encourage pregnant women, those who may become pregnant, breastfeeding mothers, and young children to eat more fish and to eat a variety of fish from choices that are lower in mercury. FDA's acting chief scientist Dr. Stephen Ostroff said the advice addresses concerns that pregnant and nursing women were scared of eating fish and missing out on its nutritional benefits.

Other News
FDA Issues Final Rule Setting Manufacturing Standards for Infant Formula

CDC Evaluates, Ranks Superfoods

Synthetics Increasingly Used in Household Products

New Survey on America's Diet Beliefs and Behaviors

Study: Prohibiting Food Stamps for Sugary Beverages Linked to Reduced Diabetes Risk

China Buying International Food Producers at Record Pace

School Meals Nutrition Debate Continues

Panera Bread will remove artificial ingredients by 2016

Regulatory Updates

FDA Issues Final Rule on Infant Formula Standards
In the June 10 *Federal Register*, FDA issued final regulations for infant formula standards, including current good manufacturing practices, quality control procedures, quality factors, notification requirements, and records and reports. The final rule adopts, with some modifications, the interim final rule issued in February and will become effective July 10. A companion guidance for demonstrating the quality factor requirements was announced in the same *Federal Register*. FDA additionally issued a constituent update and consumer update explaining the requirements of the final rule.

FDA Confirms Increase in Civil Monetary Penalties Effective June 18
In the June 6 *Federal Register*, FDA confirmed the direct final rule revising the regulations on civil penalties will be effective on June 18. The direct final rule adjusts the penalty amounts for inflation and amends the process for initiating certain civil penalty administrative actions. The direct final rule was published in February. FDA is required to adjust the CMP at least once every four years under the Federal Civil Penalties Inflation Adjustment Act of 1990. The rule increased the maximum CMP amount anywhere from $1,000 to $25,000 per individual, $10,000 to $25,000 per violation, and $50,000 to $850,000 for multiple violations being adjudicated in a single proceeding.

USDA Proposes Rule Adding Terms for Biologics to Animal Test Results
In the May 30 *Federal Register*, USDA's Animal and Plant Health Inspection Service proposed amending the veterinary biological product regulations by defining the terms used for reporting the results of tests performed on such products. USDA says defining these terms will clarify the circumstances under which the results of a prescribed test can be reported as satisfactory, unsatisfactory, inconclusive, or a No Test. ***Comments due July 29.***

FDA Publishes Compliance Policy Guide Regarding Food Facility Registration
In the June 3 *Federal Register*, FDA announced the availability of its *Compliance Policy Guide Regarding Food Facility Registration for Human and Animal Food*. The Guide provides guidance for FDA staff on enforcement of food facility registration requirements.

USDA Responds to Comments on Raw Beef Testing for Pathogens
In the June 5 *Federal Register*, USDA responded to public comments on its August 2013 document *Changes to Salmonella Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing Escherichia coli and Salmonella*. USDA's response announced plans to begin analyzing all beef products for *Salmonella* when it performs Shiga toxin-producing *E. coli* tests. The response affirms FSIS's plans for addressing *Salmonella* in raw beef products announced in the document.

FDA and EPA Announce Draft Update on Mercury and Fish Consumption
On June 9, FDA and EPA jointly announced the update of 2004 advice regarding *What You Need to Know About Mercury in Fish and Shellfish*. The draft update appears in the June 11 *Federal Register*. The update contains both advice and supplemental questions and answers that go into more detail than the previous version of the document. Notably, the agencies adopt the *Dietary Guidelines for Americans 2010*, recommending that pregnant women and women who might become pregnant eat at least eight ounces of fish per week, provided the fish variety is low in mercury.

FDA Announces the Following Approved Information Collections
Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

Request for Information from United States Processors that Export to the European Community

Pet Event Tracking Network-State, Federal Cooperation to Prevent Spread of Pet Food Related Diseases

FDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Focus Groups as Used by the FDA for all FDA-Regulated Products (***comments due July 7***)

Regulations for Voluntary Grading of Shell Eggs, Poultry Products, and Rabbit Products (***comments due July 7***)

Karnal Bunt; Importation of Wheat and Related Articles (***comments due July 29***)

Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations (***comments due August 4***)

Third Party Disclosure and Recordkeeping Requirements for Reportable Food (***comments due August 4***)

USDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Dairy Request for Applicant Number (***comments due July 9***)

Meat Slaughter Industry Survey (***comments due July 9***)

Category of Plants for Planting Not Authorized for Importation Pending Pest Risk Analysis (***comments due August 4***)

Other USDA Announcements
Agricultural Marketing Orders
• Kiwifruit Grown in California (***effective May 29***)
• Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida (***comments due July 28***)

Request for Nominations to the Peanut Standard Board (***nominations due July 14***)

Availability of a Plant Pest Risk Assessment and Environmental Assessment for Preliminary Determination of Nonregulated Status of Soybean Genetically Engineered for Herbicide Resistance (***comments due June 30***)

Availability of a Plant Pest Risk Assessment and Environmental Assessment for Determination of Nonregulated Status of Potato Genetically Engineered for Low Acrylamide Potential and Reduced Black Spot Bruise (***comments due June 30***)

Availability of a Plant Pest Risk Assessment and Environmental Assessment for Determination of Nonregulated Status of Genetically Engineered Alfalfa (***comments due June 30***)

National Sheep Industry Improvement Center (***comments due July 3***)

Notice of Affirmation of Addition of a Treatment Schedule for Methyl Bromide Fumigation of Kumquat (***effective June 4***)

Final Rule: Importation of Female Squash Flowers From Israel

National Genetic Research Advisory Council (***nominations due June 13***).

Upcoming Meetings, Workshops, and Conferences

Meeting of the Codex Alimentarius Commission, **June 18**, in Geneva, Switzerland.

USDA Secretary's Advisory Committee on Animal Health, **June 18–19**, in Washington, DC.

Public Meeting on Proposed Rules on Nutrition and Supplement Facts Labels, **June 26**, in Washington, DC.

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

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

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

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

Enforcement Updates

Recent Product Recalls

Bacterial contamination was the primary reason behind most food recalls over the last two weeks. Two dog food products were recalled for *Salmonella* contamination, as were chia seed and flaxseed powder products, ground pepper, and snack crackers. Minced crab meat was recalled for *Listeria* contamination. A dietary supplement maker also recently issued an expanded recall for its products that may contain undeclared pharmaceutical ingredients. Two companies issued a recalls of products packed in the wrong container that does not warn consumers that the product contains nuts. Lamb and sheep feed was recalled for high copper content.

USDA posted only one recall over the last two weeks: 363 pounds of boneless skinless chicken breasts with teriyaki seasoning were recalled due to misbranding because the product was formulated with wheat, yet the label claimed the product was gluten free.

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 facilities for drug residues in edible tissues of animals sold for slaughter. FDA posted three such letters over the last two weeks. Seafood processing facilities also remain targets of FDA inspections with two letters posted for HACCP/CGMP violations for insufficient critical control points and limits that comply with regulations for temperature and acidity. FDA additionally posted three warning letters to the makers of several dietary supplements for therapeutic claims rendering the product a drug under the Food, Drug, and Cosmetic Act.

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