JONES DAY

Food, Dietary Supplement & Cosmetics Regulatory Update
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FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

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In Settlement With CFS, FDA Agrees to Finalize Rule for GRAS Determination Process
Earlier this month, the Center for Food Safety ("CFS") announced it had reached a settlement agreement with FDA requiring the agency to finalize the interim policy for its generally recognized as safe ("GRAS") food additive approval process by the end of August 2016. In February of this year, CFS sued FDA for operating the GRAS food additive process under a proposed rule since 1997, alleging FDA had failed to properly regulate food additives by operating under a proposed rule rather than finalizing it. FDA reopened the comment period for the proposed rule on December 28, 2010, but has yet to issue a final rule. Instead, for 17 years, FDA has operated under the interim policy CFS argues is a "lax regulatory system" falling "far short of what is required to protect consumers from potentially unsafe food additives." Furthermore, because the proposed rule is not final agency action, it cannot be challenged in court, frustrating the efforts of anyone who wishes to dispute the 1997 GRAS scheme.

The settlement agreement requires FDA to submit a final rule regarding GRAS substances to the Federal Register no later than August 31, 2016. The settlement provides a procedure by which FDA can request an extension of the deadline. If FDA fails to meet its deadline and has not sought to modify it, CFS can move the court to enforce the terms of the settlement.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), any substance that is intentionally added to food is considered a food additive and subject to premarket review and approval by FDA, unless the substance is GRAS, meaning the substance is generally recognized among qualified experts to be safe under the conditions of its intended use. Organizations may demonstrate a food additive is GRAS in one of two ways: (i) through scientific procedures showing general recognition of safety; or (ii) for additives used in food before 1958, through experience based on common use in food.
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Tainted Supplements Continue to Be Sold After Recalls, Study Shows
According to a study published in the Journal of the American Medical Association, tainted dietary supplements often continue to be spiked with hidden and potentially dangerous drugs even after product recalls. Specifically, the study identified 27 supplements sold online during the summer of 2013 that were among the 274 products recalled between 2009 and 2012. Researchers found that 67 percent of the sampled supplements contained at least one drug ingredient, including active ingredients used in diet drugs and erectile dysfunction medicines. Eighty-five percent of sports enhancement or bodybuilding supplements remained adulterated with dangerous compounds, including anabolic steroids. The study called for more aggressive FDA enforcement with regard to dietary supplements and increased agency powers to prevent marketing of tainted supplements to consumers.

Voters in Colorado, Oregon Will Weigh in on GMO Debate
On November 4, 2014, Colorado and Oregon will decide whether foods made with genetically modified organisms ("GMOs") must bear identifying labels. Ballot measures in both states call for labeling food that contains materials made with biotechnology. If successful, Colorado and Oregon could become the first states to pass referenda on the issue. Similar measures were defeated in Washington and California during previous election cycles. Last May, Vermont enacted a state law approving the labeling of foods containing GMOs, but the issue is still being litigated in court.

FDA Develops Online Learning Module to Help Ensure Proper Labeling of Seafood Products
According to a recent constituent update, FDA has developed an online learning module to help the seafood industry, retailers, and state regulators ensure that seafood products are properly labeled for sale in the United States. Correctly identifying seafood helps achieve appropriate food safety controls and ensures that consumers receive the actual seafood for which they paid. The module provides an overview of federal labeling requirements, tips for identifying mislabeled seafood, and a list of governing laws, regulations, and guidance documents.

Other News
FDA to Hold Public Meeting on Changes to FSMA Proposed Rules

FDA to Hold Public Meeting on Updates to Redbook

FDA Builds Closer Ties with Mexico to Ensure Imported Foods from Mexico Meet U.S. Standards

Citizen Petition Asks FDA to Ban Toxins in Pizza Boxes

Undeclared Allergens Are Leading Cause of Food Recalls

Regulatory Updates

FDA to Hold Public Meeting on Revisions to Proposed FSMA Rules
In the October 23, 2014, *Federal Register*, FDA announced a public meeting to discuss proposed revisions to some of the proposed rules implementing the FDA Food Safety Modernization Act ("FSMA"). In response to public comments on the foundational rules, FDA issued supplemental notices of proposed rulemaking describing significant changes to four of the proposed rules introduced in 2013. The supplemental notices revise the rules concerning preventive controls for human food, produce safety, preventive controls for animal food, and foreign supplier verification programs. The public meeting, scheduled for **November 13, 2014**, in College Park, MD, will solicit oral stakeholder and public comments on the new content of the supplemental proposed rules. ***Electronic and written comments due December 15, 2014***.

FDA to Hold Public Meeting on Updates to Redbook
In an October 29, 2014, notice, FDA announced it will hold an open meeting to receive input from the public on updating the "Guidance for Industry: Toxicological Principles for the Safety Assessment of Food Ingredients," also known as the "Redbook." FDA is soliciting ideas on what should be included, changed, or removed from the current Redbook, and the agency is considering expanding the scope of the Redbook to include chemical safety assessments for all products over which the Center for Food Safety and Applied Nutrition has statutory authority: food additives, food contact substances, dietary supplement ingredients, food contaminants, and cosmetics. The public meeting is scheduled for **December 9, 2014**, in College Park, MD. ***Electronic and written comments due February 9, 2015***.

USDA Proposes Rule to Clarify Requirements on USDA-Donated Foods
In the October 22, 2014, *Federal Register*, USDA announced a proposed rule to revise and clarify requirements governing the distribution, storage, and management of foods donated by USDA to state and local agencies for various food assistance programs. The proposal would reduce administrative and reporting requirements for state distributing agencies and implement other changes to make program controls more efficient. In formulating the proposals, USDA's Food and Nutrition Service consulted with program administrators, industry representatives, and other organizations. ***Comments due January 20, 2015***.

USDA Announces Revisions to U.S. Standards for Certain Onions to Allow Mixed Packing
In the October 23, 2014, *Federal Register*, USDA issued two final rules revising the U.S. Standards for certain grades of onions: (i) Onions and Bermuda-Granex-Grano Type Onions and (ii) Creole Type Onions. The rules amend certain requirements to allow mixed colors of onions when designated as a mixed or specialty pack. ***The changes are effective November 24, 2014***.

FDA Announces Filing of Color Additive Petition for Spirulina Extract
In the October 22, 2014, *Federal Register*, FDA announced its filing of a citizen petition proposing the color additive regulations be amended to provide for the safe use of spirulina extract as a color additive in coating formulations applied to dietary supplement tablets and capsules.

FDA Announces Filing of Food Additive Petition for Use of Dried Algae in Dog Food
In the October 16, 2014, *Federal Register*, FDA announced its filing of a citizen petition proposing the food additive regulations be amended to provide for the safe use of *Schizochytrium sp*. dried algae as a source of docosahexaenoic acid for use in standard pelleted foods for adult dogs. ***Comments due November 17, 2014***.

USDA Issues Rule Allowing Import of Unshu Oranges from Japan into the United States
In the October 27, 2014, *Federal Register*, USDA issued a final rule amending the citrus fruit regulations to remove certain restrictions on the importation of Unshu oranges from Japan. Specifically, the proposal removes requirements for the fruit to be grown in specified canker-free export areas with buffer zones and clarifies certain phytosanitary requirements. ***The rule is effective November 26, 2014***.

USDA Proposes Allowing Import of Kiwi from Chile into the United States
In the October 15, 2014, *Federal Register*, USDA issued a proposed rule to amend the fruits and vegetables regulations to list kiwi (*Actinidia deliciosa* and *Actinidia chinensis*) from Chile as eligible for importation into the United States subject to a systems approach. The systems approach would require fruit for import to be grown in a place certified as having a low prevalence of *Brevipalpus chilensis* and to undergo pre-harvest sampling. ***Comments due December 15, 2014***.

FDA Information Collection Activities

FDA Announced the Following Information Collections Have Been Submitted to OMB:
State Petitions for Exemption from Preemption

USDA Information Collection Activities

USDA Announced the Opportunity to Comment on the Following Proposed Information Collections:
Noninsured Crop Disaster Assistance Program

USDA Announced the Opportunity to Comment on the Following Approved, Revised, and/or Extended Information Collections:
Endangered Species Regulations and Forfeiture Procedures

Lacey Act; Definitions for Exempt and Regulated Articles

Notice of Emergency Approval of New Information Collection for Feasibility of Tribal Administration of Federal Nutrition Assistance Programs

Unpaid Meal Charges

Supplemental Nutrition Assistance Program Revision of the Program and Budget Summary Statement Part B-Program Activity Statement

Other USDA Announcements:
Opportunity for Designation in Casa Grande, AZ; Jamestown, ND; Lincoln, NE; Memphis, TN; and Sioux City, IA Areas; Request for Comments on the Official Agencies Servicing These Areas

Notice of Decision to Authorize the Importation of Chipilin Leaves and Edible Flowers of Chufle, Izote, and Pacaya From Guatemala into the Continental United States

Notice of Guidance Regarding the Specialty Crop Block Grant Program, Multi-State Project Competition

Upcoming Meetings, Workshops, and Conferences

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

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

Meeting of the Grain Inspection Advisory Committee, **November 5, 2014**, in Kansas City, MO.

Sixth 2015 Meeting of USDA's Dietary Guidelines Advisory Committee, **November 7, 2014**, via webcast only.

Meeting on Food and Drug Administration Food Safety Modernization Act, **November 13, 2014**, in College Park, MD.

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

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.

Enforcement Updates

Recent Product Recalls
Manufacturers recently recalled cosmetics, foods, and a dietary supplement product, primarily due to bacterial contamination and undeclared allergens. In a rare cosmetics recall, a manufacturer initiated a nationwide recall of its baby wipe products after complaints about the odor and discoloration of the product led the company to investigate and determine the presence of a potentially harmful bacteria.

Several USDA- and FDA-regulated food products and a dietary supplement product were recalled due to potential *Salmonella* or *Listeria* contamination. FDA-regulated companies continue to recall products for a failure to declared major allergens (such as milk, soy, or tree nuts). Increasingly, USDA-regulated products are also being recalled for this reason. Lastly, one company recalled certain lots of raw lamb products because they were imported without USDA inspection.

View a complete list of product recalls for FDA-regulated products and USDA-regulated products.

Recent Warning Letters
FDA continues to review product labels and websites for misleading claims. In recent warning letters, the agency cited two manufacturers for product labels and website descriptions bearing implied nutrient content claims for products that did not meet the requirements for such claims. The manufacturers marketed their coconut butter and Greek yogurt as "healthy" but exceeded the maximum saturated fat amounts allowed for a "healthy" claim.

Three canned food processors were warned for various violations of the Acidified Foods, Low-Acid Canned Foods, and Emergency Permit regulations. One such company failed to provide scheduled process information about heat processing and controls for pH and preservative levels, and another processor shipped finished products that were not manufactured according to temperature controls. One company, based in China, was additionally cited for not complying with inspection requirements and for labeling a Pacific herring product as sardines. The agency also cited three seafood processing facilities for HACCP (hazard analysis and critical control points) violations and sent warning letters to three dairy farms, two cattle farms, and a pig farm for illegal drug residue found in livestock sold for slaughter.

In addition, a dietary supplement manufacturer was warned for CGMP (current good manufacturing practice) violations and for failing to label its products as "dietary supplements."

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

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