JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
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Top News

FDA Amends Nutrition and Supplement Facts Labels
Effective July 26, 2016, FDA is amending its labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The results of this regulation will be very visible to consumers, since it will change the format and content of the familiar "Nutrition Facts" panel that appears on all packaged foods. The changes are intended to reflect new knowledge of nutritional science, to better reflect the amounts of food people commonly eat per "serving," and to better inform consumers to help them achieve nutrition and weight-loss goals. The new rules were publicized by an announcement from First Lady Michelle Obama.

The final rule: (i) updates the list of nutrients that are required or permitted to be declared; (ii) provides updated Daily Reference Values ("DRV") and Reference Daily Intake values ("DV") that are based on current dietary recommendations from consensus reports; (iii) amends requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant and lactating women, and establishes nutrient reference values specifically for these population subgroups; and (iv) revises the format and appearance of the Nutrition Facts label. Some of these suggested changes include larger type calorie counts and serving sizes, and the declaration of the gram amount and percent DV of "added sugars" in a serving of a product.

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FDA stated the updated information is consistent with current data on the associations between nutrients and chronic diseases, health-related conditions, physiological endpoints, and/or maintaining a healthy dietary pattern that reflects current public health conditions in the United States, and corresponds to new information on consumer understanding and consumption patterns. *See* 2014 FDA Health and Diet Survey, published on May 6, 2016.

In addition, FDA has issued another final rule to: (i) define a single-serving container; (ii) require dual-column labeling for certain containers; (iii) update, modify, and establish several reference amounts customarily consumed; (iv) amend the label serving size for breath mints; and (v) make technical amendments to various aspects of the serving size regulations. For both final rules, the compliance date is July 26, 2018, for manufacturers with $10 million or more in annual food sales, and July 26, 2019, for smaller manufacturers.

FDA Issues Final Guidance Regarding Food Labeling Term "Evaporated Cane Juice"

On May 24, 2016, FDA released a final guidance stating sweeteners derived from sugar cane, including those derived from sugar cane syrup, should not be declared on food labels as "evaporated cane juice." FDA's view is that the term "evaporated cane juice" is false or misleading because it suggests the sweetener is or is made from fruit or vegetable juice and does not reveal that the ingredient's basic nature and characterizing properties are those of a sugar. These conclusions largely echoed statements in a draft guidance of FDA published in 2009. With "evaporated cane juice" food label class action lawsuits becoming common in federal court, FDA reopened the comment period in 2014 requesting further data about the basic nature and characterizing properties of the ingredient labeled as "evaporated cane juice," how this ingredient is produced, and how it compares with other sweeteners. After reviewing the data and comments received, FDA is recommending that ingredients currently labeled as "evaporated cane juice" be relabeled to use the term "sugar." At the manufacturer's option, the term "sugar" can be accompanied by a truthful, nonmisleading descriptor to distinguish the ingredient from other cane-based sweeteners. The notice of availability for the guidance document will publish in the May 26, 2016, *Federal Register*. For more information regarding food label litigation, including litigation focusing on "evaporated cane juice," see our Jones Day *Commentary*: "Will Evaporated Cane Juice Be Sweet for Class Action Plaintiffs?"

FDA Lets Kind Use "Healthy" on Snack Bar Labels

FDA recently told Kind LLC that it may label its fruit-and-nut snack bars as "healthy and tasty" as long as the phrase is clearly framed as part of its corporate philosophy and not as a nutritional statement, and the phrase does not appear on the same display panel as nutrient content claims or nutrition information. This move closes out FDA's earlier warning to the company, where the Agency found four Kind products to be "misbranded" due to the fact that their labels made nutrient content claims the products did not satisfy. Specifically, FDA argued that although the Kind labels claimed the products were "healthy and tasty" (suggesting that the product could be useful in maintaining healthy dietary practices), none of the products met the requirements for use of the nutrient content claim "healthy." With its decision to Kind, FDA also confirmed that it plans to reevaluate regulations concerning nutrient content claims generally, including the term "healthy." FDA's decision follows a Citizen Petition filed by Kind last December, which requested that FDA: (i) fully reevaluate its nutrient content claim regulations to ensure consistency with federal dietary recommendations; (ii) define "dietary guidance statement" more broadly; and (iii) clarify its regulations for "general nutritional claims" and "label statements that are not implied claims." FDA currently allows use of the term "healthy" on food labels if the product meets certain conditions for fat, saturated fat, cholesterol, and other nutrient levels.

Group of Republican Senators Push FDA on Draft Guidance Review

On May 6, 2016, four Republican senators—Lamar Alexander (TN), Richard Burr (NC), Johnny Isakson (GA), and Orrin Hatch (UT)—sent a letter to FDA Commissioner Robert Califf expressing concerns over the amount of time it takes FDA to revise, finalize, or withdraw draft guidance documents. The letter follows FDA's response to a 2014 letter by the same group of senators, which sought clarification regarding FDA's use of draft guidance to make substantive policy changes. Both letters argue that leaving guidance documents in draft form for so long, sometimes for years, makes it difficult to know whether FDA remains committed to the policies outlined in old draft documents. According to FDA's response to the 2014 letter, the Center for Food Safety and Applied Nutrition ("CFSAN") had 16 pending draft guidance documents as of December 31, 2013, and it took CFSAN between 90 and 1,502 days (a median of 454 days) to finalize draft guidance documents.

The 2016 letter, while acknowledging FDA's response, requests that FDA provides updates on: (i) the median number of days it takes FDA to finalize draft guidance; (ii) the list of guidance documents still pending finalization; (iii) the plan for FDA Centers and Offices to systematically review outstanding and future draft guidance documents in a timely manner; (iv) the method used to train FDA staff and employees about how to use draft guidance documents, including information about who conducts these trainings, how frequently they occur, and the content and forum of the trainings; and (v) whether a draft guidance document that has not been finalized should be construed as reflecting FDA's current thinking.

Senate Committee Approves Agriculture and FDA Appropriations Bill
On May 19, 2016, the Senate Committee on Appropriations unanimously approved a $147.7 billion appropriations bill to support federal agriculture and nutrition programs in FY2017. Among other things, the bill would grant: (i) $2.54 billion to support agricultural research, including $375 million for the Agriculture and Food Research Initiative; (ii) $1.518 billion to the Farm Service Agency for various farm, conservation, and emergency loan programs; (iii) $1.033 billion to the Food Safety and Inspection Service, supporting more than 8,000 frontline inspection personnel for meat, poultry, and egg products at more than 6,400 U.S. facilities; (iv) $2.759 billion in discretionary funding to FDA, including a $40.2 million increase for food safety activities; and (v) more than $100 billion for food and nutrition programs. The bill is now available for consideration before the full Senate.

U.S. Complains to WTO on China's Illegal Chicken Duties
In its long trade dispute with China, the United States recently reported to the World Trade Organization ("WTO") that the Chinese government continues to impose high import duties on U.S. chicken broiler products, breaching the WTO anti-dumping and countervailing rules. The dispute, which was resolved by the WTO in September 2013 in favor of the United States, was followed by China's reinvestigation of its anti-dumping and countervailing duties against U.S. chicken imports. In 2014, China decided to lower some of these duties. However, the U.S. claims China's investigation lacked transparency and failed to properly calculate costs of poultry production for U.S. producers. U.S. Trade Representative Michael Froman said the challenge would hold China accountable for unfair taxes imposed on American exports of broiler chicken products. China's Ministry of Commerce stated that it is willing to resolve the dispute in accordance with WTO procedures.

European Parliament Calls for Mandatory Country of Origin Labeling of Meat and Milk Products
On May 15, 2016, the European Parliament ("Parliament") adopted a nonbinding resolution calling for the European Commission ("Commission") to come up with legislative proposals regarding the country of origin or place of provenance labeling for all kinds of drinking milk, dairy products, and processed meat products. According to the Parliament, the Commission should also consider extending it to single-ingredient foods, or to foods with one main ingredient. The Parliament stated that mandatory country of origin labeling is necessary to better inform EU consumers and to improve transparency

throughout the food chain. A mandate for the Commission to assess the need for such legislative proposals is provided in Regulation 1169/2011.

European Parliament's Committee Calls for Greater Regulation of Food Contact Materials
On May 5, 2016, the Environmental Committee of the Parliament published a draft recommendation urging the Commission to address gaps in enforcement measures and the risk assessment and traceability of food contact materials ("FCMs"). In particular, the draft report calls for the harmonization of the rules for FCMs at the EU level and asks the European Food Safety Authority to assess FCMs' safety by considering multiple exposures from different chemicals with and without similar toxicological endpoints. In addition, the report provides that Member States should carry out controls more efficiently, and companies should always submit a declaration of compliance to certify their FCMs meet regulatory standards. The Committee will vote on the final recommendation in July 2016.

Other News
FDA Issues Guidance for Industry on Use of Material from Deer and Elk in Animal Feed

Natural Resources Defense Council Requests EPA to Take Dow AgroScience LLC's Weed Killer Off the Market

USDA Increases Sugar Imports Over GE Labeling Legislation Uncertainty

Canada Approves Sale of GMO AquAdvantage Salmon

Regulatory Updates

FDA Issues Newer Version of Medical Foods Frequently Asked Questions Guidance
In the May 13, 2016, *Federal Register*, FDA announced the availability of a guidance for industry titled "Frequently Asked Questions About Medical Foods; Second Edition." A medical food is a food formulated to be consumed or administered under the supervision of a physician and that is intended "for the specific dietary management of a disease or condition" for which distinctive nutritional requirements are established by medical evaluation. FDA published earlier versions of the guidance in May 1997 and May 2007. The second edition of the guidance provides responses to additional questions regarding the definition and labeling of medical foods and updates some prior responses. For instance, FDA clarifies that medical foods that bear a false or misleading claim would be considered misbranded under section 403(a)(1) of the FD&C Act. In addition, FDA updates its response regarding diabetes, stating that there are no distinctive nutritional requirements associated with the management of diabetes mellitus ("DM"), but nutritional recommendations have been established for persons to manage it. FDA still maintains that DM can be managed by a modification of diet alone, and hence medical foods cannot be marketed for the treatment of diabetes.

FDA Files Food Additive Petition
In the May 20, 2016, *Federal Register*, FDA announced the filing of a food additive petition submitted by the Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council. The petition proposes that FDA amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates. ***Comments are due July 19, 2016***.

FDA Issues Guidance on Menu Labeling
As anticipated in our previous Jones Day *Update*, in the May 5, 2016, *Federal Register*, FDA announced availability of a guidance titled "A Labeling Guide for Restaurants and

Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance With FDA's Food Labeling Regulations)." The guidance will help certain restaurants and similar retail food establishments comply with menu labeling requirements, including the requirements to provide calorie and other nutrition information for standard menu items, food on display, and self-service food. Enforcement of the Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments final rule will commence one year after the date on which this document publishes in the *Federal Register*.

FDA Corrects Final Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
In the May 3, 2016, *Federal Register*, FDA amended the final rule on science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. FDA established these standards as part of the implementation of the FDA Food Safety and Modernization Act. The final rule published with some editorial and inadvertent errors. The new document corrects those errors, ***effective May 3, 2016***.

FDA Issues Draft Guidance "Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)"
In the May 16, 2016, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)." This draft guidance explains how to determine whether a business is a "qualified facility" that is subject to modified requirements under the Preventive Controls for Human/Animal Food Rules. This draft guidance also explains FDA's current thinking on how a business would submit Form FDA 3942a or Form FDA 3942b attesting to its status as a qualified facility under the Preventive Controls for Human Food Rule or the Preventive Controls for Animal Food Rule, respectively. ***Comments are due July 15, 2016***.

FNS Proposes Rule to Amend Disaster Supplemental Nutrition Assistance Program
In the May 10, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS") proposed to amend its Disaster Supplemental Nutrition Assistance Program ("D-SNAP") regulations, which provide temporary food assistance for households affected by a disaster when the President issues a disaster declaration. The proposed rule addresses: (i) the development of a disaster plan; (ii) the circumstances necessary for approval of a D-SNAP; (iii) the required content of the state request to FNS for a D-SNAP; (iv) the basic eligibility and benefit policy for participation in D-SNAP; (v) the application processing requirements for D-SNAP; (vi) the policy regarding currently certified SNAP participants residing in disaster areas; (vii) the monitoring states' D-SNAP operations; and (viii) state reporting on D-SNAP (both during and at the conclusion of disaster operations). ***Comments are due July 11, 2016***.

APHIS Proposes Rule for Importation of Lemons from Northwest Argentina
In the May 10, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") proposed to allow the importation of lemons from northwest Argentina into the continental United States. As a condition of entry, the lemons would have to be produced in accordance with a systems approach that would include: (i) requirements for importation in commercial consignments; (ii) registration and monitoring of places of production and packinghouses; (iii) pest-free places of production; (iv) grove sanitation, monitoring, and pest control practices; (v) treatment with a surface disinfectant; (vi) lot identification; and (vii) inspection for quarantine pests by the Argentine national plant protection organization. In addition, lemons would have to be harvested green (within a certain time period) or treated for the Mediterranean fruit fly, and be accompanied by a

certificate stating that the lemons have been inspected and found to be free of quarantine pests. ***Comments are due July 11, 2016***.

AMS Proposes to Revise U.S. Standards for Grades of Cauliflower
In the May 9, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") proposed to revise the U.S. standards for grades of cauliflower, to allow all colors of cauliflower (including purple, orange, and green) to be certified to a U.S. grade. In addition, AMS proposed to: (i) amend the size requirement to allow curds of less than four inches in diameter to be certified to a grade; (ii) add marking requirements to sizes of less than four inches in diameter; and (iii) remove the unclassified section. ***Comments are due July 8, 2016***.

AMS Revises U.S. Standards for Grades of Canned Baked Beans
In the May 9, 2016, *Federal Register*, AMS revised U.S. standards for Grades of Canned Baked Beans to replace process-specific language with language reflective of current canned baked bean manufacturing practices. Additionally, AMS separated the canned dried beans, canned pork and beans, and canned baked beans grade standards from one shared standard document into three separate documents, bringing the standards for canned baked beans in line with the present quality levels being marketed today and providing guidance in the effective use of these products. ***The rule is effective June 8, 2016***.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the Advisory Committee on Biotechnology and 21st Century Agriculture, **June 13–14, 2016**, in Washington, D.C.

Public Meetings of FDA to discuss implementation of the FDA Food Safety Modernization Act import safety programs, **June 7, 2016**, in Costa Mesa, CA; **June 15, 2016**, in Rutherford, NJ; and **June 21, 2016**, in Detroit, Michigan.

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