JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
Vol. III | Issue 13 | October 2016 JONES DAY

Top News

FDA Announces Public Process to Redefine Use of Term "Healthy" in Food Labeling
On September 28, 2016, FDA announced it has started a public process to redefine the "healthy" nutrient content claim for food labeling. On December 1, 2015, FDA received a citizen petition requesting it amend the regulation defining the claim with respect to total fat intake and amend the regulation to emphasize whole foods and dietary patterns rather than specific nutrients. As a result, FDA has established a docket to receive information and comments on the use of this term generally, and as a nutrient content claim in the context of food labeling. FDA has also invited interested persons to comment on certain questions included at the end of the *Federal Register* request for comments notification. The comment period ends January 26, 2017. While FDA considers the comments and how to redefine the term, food manufacturers can use the term "healthy" on food that meet the current regulatory definition. Additionally, FDA has issued a guidance for industry titled "Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance for Industry," where FDA advises food manufacturers of its intent to exercise enforcement discretion with respect to the claim "healthy" on foods that have a fat profile of predominantly monounsaturated and polyunsaturated fats but do not meet the regulatory definition of "low fat," or that contain at least 10 percent of the Daily Value per reference amount customarily consumed of potassium or vitamin D.

CONTACTS

Edgar J. Asebey
Miami

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Jonathan Berman
Washington

Françoise S. Labrousse
Paris

Katherine M. Llewellyn
Brussels

Ales Bartl
Brussels

Laura E. Koman and Marina E. Moreno of the Washington Office assisted in the preparation of this Update.

Detailed Contact Information

RELATED PRACTICES

FDA Regulatory & Compliance Counseling

Health Care

Life Sciences

FDA stated it is reevaluating the regulatory criteria for use of the implied nutrient content claim "healthy" in light of the latest nutrition science and current dietary recommendations, reflected in the 2015–2020 *Dietary Guidelines for Americans*. In these guidelines, scientific understanding and nutrition guidance has shifted from recommending diets low in total fat to no longer recommending limiting overall fat intake, and instead prioritizing increasing intakes of polyunsaturated and monounsaturated fats and decreasing intakes of saturated fat and trans fat. Additionally, FDA intends to update its regulations to be consistent with the final Nutrition Facts Label Rule. The guidance is immediately effective.

Ninth Circuit Reverses Summary Judgment Regarding Dole's "All-Natural Fruit" Labeling but Affirms Decertification of the Damages Class

On September 12, 2016, in an unpublished disposition, the Ninth Circuit reversed in part a district court's ruling that "All Natural Fruit" labeling on Dole Food Co. products was unlikely to deceive consumers. The plaintiff, Chad Brazil, who sought to represent a class of consumers, alleged that Dole's food products labeled with "all-natural" claims would deceive a reasonable consumer as they contained synthetic ingredients, such as ascorbic acid and citric acid. Brazil cited FDA's informal definition of "natural," which means "that nothing artificial or synthetic … has been included in, or has been added to, a food that would not normally be expected to be in the food," and FDA's latest warning letters to food sellers for describing their products as "100% Natural" or "All Natural" when such products contained synthetic citric acid, among other substances. In this case, Brazil alleged that although both substances, ascorbic acid and citric acid, are found naturally in citrus fruits, these are mass-produced and added to fruit products as preservatives. The Ninth Circuit concluded that the introduction of both substances in Dole's products were not "natural" and that "the evidence could allow a trier of fact to conclude that Dole's description of its products as 'All Natural Fruit' is misleading to a reasonable consumer."

But while the Ninth Circuit permitted the plaintiff to further pursue his claims, the court affirmed significant restrictions on the available theories and remedies. The plaintiff had sought damages equaling the full purchase price of every allegedly deceptively labeled product that the class had purchased. He argued that he was entitled to this remedy because a misbranded product is not just illegal to sell but illegal to buy and hold, potentially subjecting unsuspecting consumers to fines or prosecution. The District Court had dismissed this claim, and the Ninth Circuit affirmed, calling this theory "outlandish." The Ninth Circuit further held that since the products were not worthless, plaintiff could not demand a full refund. Rather, the damages available are limited to the "price premium"—"the difference between the prices customers paid and the value of the fruit they bought." Since the plaintiff had no methodology that would permit calculation of this premium across the class, the District Court was correct to decertify the damages class.

The Ninth Circuit remanded the case to allow the plaintiff to pursue injunctive relief on behalf of the class, and to pursue his remaining individual claim for restitution. For additional detail regarding the litigation, see the Jones Day *Alert*, "Ninth Circuit Affirms Class Decertification Order but Reverses Summary Judgment in 'All Natural' Foods Label Case."

FDA Issues Guidance on Food Facility Registration Product Categories

On September 26, 2016, FDA issued the guidance "Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories," amending the food product categories available for registration of food facilities. Some of the food product categories that have been amended are: (i) acidified foods and low-acid canned foods, which are no longer listed as food product categories but activity types; (ii) the animal food categories, which now add botanicals and herbs, direct-fed microbials, animal protein products, forage products, human food by-products not otherwise listed and technical additives (the "animal protein products" category replaces the previous "animal derived products" category, and the "processed animal waste products" category replaces the "recycled animal waste products" category); and (iii) the molluscan shellfish optional activity type, which is now a food product category. FDA

stated these amendments will help the agency's ability to respond quickly and accurately to food-related emergencies and to verify that imported products are correctly identified by where and when they were produced.

Other News
The Food and Agriculture Organization Issues Action Plan on Antimicrobial Resistance

The United States and 12 other WTO Members to Negotiate New Rules to Prohibit Fishing Subsidies

The United States Files New Complaint at the WTO Challenging Excessive Chinese Support for Rice, Wheat, and Corn

Regulatory Updates

FDA Announces Effective Date for Definition of "Qualified Auditor" Under FSMA
In the September 19, 2016, *Federal Register*, FDA announced the effective date for the definition of "qualified auditor" included in 21 C.F.R. § 117.3 (80 FR 55098 at 56147) and § 507.3 (80 FR 56170 at 56339). The definition of "qualified auditor" was included in the final rule for "Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" of September 17, 2016, which reads, "An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter." The preamble of the rule stated that FDA would announce the effective date for the definition once it finalized the rule, "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits to Issue Certifications." Such final rule was published on November 27, 2015, with an effective date of January 26, 2016, and thus FDA announced ***the definition's effective date was September 19, 2016***.

FDA Requests Comments on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals
In the September 13, 2016, *Federal Register*, FDA requested comments regarding the establishment of appropriately targeted durations of use of antimicrobial drugs of importance to human medicine (i.e., medically important antimicrobial drugs) when they are administered in the feed or water of food-producing animals for therapeutic purposes. In March 2015, FDA developed "The National Action Plan for Combating Antibiotic-Resistant Bacteria," a plan presenting a strategy for collaborative action by the U.S. government in coordination with individuals and organizations within the human and animal health sectors with the goal of implementing interventions that can reduce the spread of antimicrobial resistance. The plan was developed in response to President Obama's 2014 Executive Order 13676 on "Combating Antibiotic-Resistant Bacteria." ***Comments are due December 13, 2016***.

FDA Files Color Additive Petition for Safe Use of Spirulina Extract
In the September 16, 2016, *Federal Register*, FDA announced the filing of a petition, submitted by McCormick & Company, Inc., that proposes that the color additive regulations be amended to provide for the safe use of spirulina extract to color shell eggs at levels consistent with good manufacturing practice. The color additive petition was filed on August 24, 2016.

FDA Approves Sodium Formate as Feed Acidifying in Swine Feeds
In the September 30, 2016, *Federal Register*, FDA issued a final rule amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of feed-grade sodium formate as a feed-acidifying agent in complete swine feeds. This action is in response to a food additive petition filed by BASF Corp. ***The rule was effective September 30, 2016, and objections and hearing requests are due October 31, 2016***.

USDA Amends Regulations Used to Administer the Facility Guarantee Program
In the September 22, 2016, *Federal Register,* USDA's Foreign Agricultural Service and Commodity Credit Corporation amended the regulations used to administer the Facility Guarantee Program ("FGP"). Under the FGP, the Commodity Credit Corporation may issue payment guarantees in connection with sales of goods or U.S. services to establish or improve agricultural-related facilities in emerging markets to expand exports of U.S. agricultural commodities or products. This final rule incorporates statutory changes from the Food, Conservation, and Energy Act of 2008 and modifications intended to reduce the burden on participants and improve program efficiency and effectiveness. Certain revisions will ensure the FGP is operated in compliance with the Organisation for Economic Co-operation and Development Arrangement on Officially Supported Export Credits. Additionally, this final rule incorporates significant changes previously made to the regulations for the Export Credit Guarantee Program that are also applicable to the FGP. ***The rule was effective September 22, 2016, but comments are accepted until March 21, 2017***.

FNS Announces Regulatory Implementation of OMB's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
In the September 28, 2016, *Federal Register*, USDA's Food and Nutrition Service ("FNS") issued a final rule amending FNS regulations to implement the Department of Agriculture's final guidance of USDA-specific requirements in the Federal Agency Regulations for Grants and Agreements. Prior to that, on December 26, 2013, the Office of Management and Budget ("OMB") published "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards." There are more than 100 references throughout 19 Parts of the FNS regulations that must be revised to accurately reference the revised OMB and USDA regulations. FNS is therefore proposing nomenclature revisions to the following Parts of Title 7: 210, 215, 220, 225, 226, 227, 235, 240, 246, 247, 248, 249, 253, 272, 273, 274, 276, and 277. ***The rule was effective September 28, 2016***.

FNS Proposes Changes to SNAP Issuance Regulations
In the September 28, 2016, *Federal Register*, USDA's FNS proposed changes to the Supplemental Nutrition Assistance Program ("SNAP") issuance regulations in accordance with the Food, Conservation, and Energy Act of 2008, Public Law 110-234 ("2008 Farm Bill"). The proposal aims to implement several provisions of the 2008 Farm Bill to: (i) clarify that monthly SNAP benefits must be issued in one lump sum; (ii) require SNAP accounts to be inactive for a minimum of six months before taking benefits offline; (iii) require benefits taken offline to be restored within 48 hours of the recipient's request; and (iv) require permanent expungement of unused benefits after 12 months of account inactivity. The proposal also addresses the requirement to notify households when benefits are taken offline. Finally, FNS is updating SNAP definitions in 7 CFR part 271, to reflect the Program's new name and the issuance of benefits through Electronic Benefit Transfer systems. ***Comments are due November 28, 2016***.

AMS Announces No Changes to Be Made to the National Dairy Promotion and Research Board
In the September 13, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") announced that no changes will be made to the current distribution of domestic National Dairy Promotion and Research Board ("Dairy Board") members in 12 regions as outlined in Section 1150.131(b) of the Dairy Research and Promotion Order ("Dairy Order"). The Dairy Order provides that the Dairy Board will review the geographic distribution of milk production throughout the United States and, if warranted, recommend to the Secretary a reapportionment of the regions and/or modification of the number of domestic members from the regions in order to better reflect the geographic distribution of milk production volumes in the United States. The number of domestic Dairy Board members was last modified in 2011 based on 2010 U.S. milk production. ***The rule was effective September 13, 2016***.

AMS Amends Regulations Governing the Voluntary Grading of Shell Eggs

In the September 16, 2016, *Federal Regiser*, USDA's AMS announced it will amend the regulations governing the voluntary grading of shell eggs to clarify the definition of "condition" and revise the prerequisite requirement for shell eggs eligible for voluntary USDA grading and certification. AMS stated that the revised definition will remove the term "wholesomeness" and state that "condition" is a characteristic detected by a sensory examination, under which presence of microorganisms, specifically *Salmonella Enteritidis* ("SE") or other pathogens, in the content of an egg cannot be detected. In addition, AMS stated that the revision of the shell egg grading program, which is designed to assist in the orderly marketing of shell eggs by providing the official certification of egg quality, size, condition, and other factors, will prohibit the use of SE-adulterated or recalled shell eggs from being presented to USDA for grading and certification. ***The rule was effective September 16, 2016***.

AMS Amends Assessment Rate of Pistachios
In the September 16, 2016, *Federal Register*, USDA's AMS implemented a recommendation from the Administrative Committee for Pistachios for a decrease in the assessment rate established for the 2016–2017 and subsequent production years from $0.0035 to $0.0010 per pound of assessed weight pistachios handled under the marketing order. ***The interim rule was effective September 19, 2016, and comments are due November 15, 2016***.

AMS Proposes Amendment to the California Raisin Marketing Order
In the September 16, 2016, *Federal Register*, USDA's AMS invited comments on a recommendation by the Raisin Administrative Committee ("Committee") to remove the term "midget" from the minimum grade standards of the California raisin marketing order. The marketing order regulates the handling of raisins produced from grapes grown in California and is administered locally by the Committee. Recently, the U.S. Standards for Grades of Processed Raisins ("standards") were amended to remove the word "midget." The proposed change would make the marketing order consistent with the amended standards. Furthermore, this rule would make a corresponding change to the raisin import regulation as required by the Agricultural Marketing Agreement Act of 1937, as amended, when changes are made to the size, grade, maturity, or quality requirements of the order. ***Comments are due October 17, 2016***.

AMS Proposes to Amend Handling Regulation and Assessment Rate of Walnuts Grown in California
In the September 16, 2016, *Federal Register*, USDA's AMS invited public comments on a proposed amendment to Marketing Order No. 984, which regulates the handling of walnuts grown in California. The California Walnut Board ("Board"), which is responsible for the local administration of the order and comprises walnut producers and handlers operating within the production area, recommended an amendment that would authorize the Board to borrow from a commercial lending institution to fund operations and marketing/research expenses. AMS stated that allowing the Committee to utilize this customary business practice would provide flexibility for the Board while increasing its effectiveness. Additionally, in the September 16, 2016, *Federal Register,* AMS proposed to implement a recommendation from the Board to increase the assessment rate established for the 2016–2017 and subsequent marketing years from $0.0379 to $0.0465 per kernelweight pound of assessable walnuts. ***Comments are due November 15, 2016, and October 17, 2016, respectively***.

AMS Amends Marketing Order for Tart Cherries Grown in Certain States
In the September 16, 2016, *Federal Register*, USDA's AMS implemented recommendations from the Cherry Industry Administrative Board to add inventory release procedures and revise optimum supply provisions under the marketing order for tart cherries grown in the states of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin. The final rule establishes procedures for releasing inventory from reserves and increases the maximum carryout volume available when calculating optimum supply from 20 million pounds to 100 million pounds. ***The rule was effective September 19, 2016***.

AMS Amends Assessment Rate of Washington Cherries
In the September 21, 2016, *Federal Register*, USDA's AMS proposed to implement a recommendation from the Washington Cherry Marketing Committee to increase the assessment rate established for the 2016–2017 and subsequent fiscal periods from $0.15 to $0.25 per ton of Washington cherries handled. ***Comments were due October 6, 2016***.

AMS Amends Assessment Rate of Domestic Dates Produced or Packed in Riverside County, California
In the September 21, 2016, *Federal Register*, USDA's AMS implemented a recommendation from the California Date Administrative Committee for a decrease in the assessment rate established for the 2016–17 and subsequent crop years from $0.10 to $0.05 per hundredweight of dates handled. ***The interim rule was effective September 22, 2016, and comments are due November 21, 2016***.

EU Regulatory Updates

EFSA Reevaluates Food Color Additives
The European Food Safety Authority ("EFSA") has completed its reevaluation of all food colors permitted for use in the European Union before 2009. Over the past seven years, EFSA's Panel on Additives and Nutrient Sources Added to Food has reassessed the safety of 41 food colors, taking into account all available scientific studies and data. Where possible, the Panel has established or updated an Acceptable Daily Intake ("ADI") for each substance. Overall, the maximum levels of three colors (E 104, E 110, E 124) were lowered, and the color Red 2G (E 128) was removed from the market. The last color additive to be evaluated has been titanium dioxide. The final reevaluation was published on September 14, 2016, and concluded that available data on use of titanium dioxide (E 171) in food does not indicate health concerns for consumers. However, EFSA recommended new studies be carried out to fill data gaps on possible effects on the reproductive system, which could require setting an updated ADI.

EFSA to Present Draft GM Plant Allergenicity Guidance to Stakeholders
On November 23, 2016, EFSA will present its draft guidance document on allergenicity of genetically modified ("GM") plants at a meeting in Parma, Italy. EFSA invites representatives of Member States, scientific experts, NGOs, industry, and international partners to participate. The assessment of potential allergenicity is an integral part of the overall risk assessment of GM plants before being commercialized in the EU.

European Commission Authorizes GMOs for Food and Feed Uses
On September 16, 2016, the European Commission authorized the sale of products containing, consisting of, or produced from GM maize Bt11 x MIR162 x MIR604 x GA21, four related GM maizes combining three different single GM events (Bt11 × MIR162 × MIR604, Bt11 × MIR162 × GA21, Bt11 × MIR604 × GA21, MIR162 × MIR604 × GA21), and six related GM maizes combining two different single GM events (Bt11 × MIR162, Bt11 × MIR604, Bt11 × GA21, MIR162 × MIR604, MIR162 × GA21, and MIR604 × GA21). These genetically modified organisms ("GMOs") have gone through a full authorization procedure, including a favorable scientific assessment by EFSA, which will be valid for 10 years. Any products produced from these GMOs will be subject to the EU's strict labeling and traceability rules. The authorization decision does not cover cultivation.

Upcoming Meetings, Workshops, and Conferences

Public Annual Meeting of the Grain Inspection, Packers and Stockyards Administration Advisory Committee, **October 19–20, 2016**, in Portland, OR.

Public Meeting of FDA to discuss menu labeling, **November 16–17, 2016**, in Oakland,

CA.

Public Meeting of the National Organic Standards Board to discuss implementation of the Organic Foods Production Act, **November 16–18, 2016**, in St. Louis, MO.

Jones Day FDA Regulatory & Compliance Counseling Contacts

Edgar J. Asebey
Miami
+1.303.714.9707
easebey@jonesday.com

Cristiana Spontoni
Brussels
+32.2.645.14.48
cspontoni@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Jonathan Berman
Washington
+1.202.879.3669
jberman@jonesday.com

Françoise S. Labrousse
Paris
+33.1.56.59.39.48
flabrousse@jonesday.com

Katherine M. Llewellyn
Brussels
+32.2.645.14.47
kllewellyn@jonesday.com

Ales Bartl
Brussels
+32.2.645.14.52
abartl@jonesday.com

Follow us on:

Jones Day is a legal institution with more than 2,500 lawyers on five continents. We are One Firm Worldwide[SM].