JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
Vol. II | Issue 9 | April 2015 JONES DAY

Top News

FDA Warns Snack Bar Company Against Using "Healthy" Labeling Claims

FDA recently cited the snack bar company KIND for using "healthy" claims on its snack bar labels. In its warning letter, FDA noted "significant violations" on the labels of various snack bars. Among other issues noted in the letter, the agency warned KIND that "the claim 'Healthy and tasty, convenient and wholesome' in connection with statements such as: 'good source of fiber,' 'no trans fats,' 'very low sodium,'" among other statements, fail to meet the FDA requirements for use of the nutrient content claim "healthy." Specifically, a food label can use the term "healthy" only if the food, among other things, has "low saturated fat" as defined in the regulations. Some of KIND's snack bars exceed these saturated fat levels.

In response, KIND (whose sales have tripled in the past three years) posted a note on its website saying it will change the labels in response to FDA's concerns. KIND also specifically addressed the "healthy" claim in the context of saturated fat, admitting that "some of our products do not follow the FDA regulatory standard for using the word 'healthy' on a label," largely due to the nut content of the snack bars. KIND then provided links to news and research on the health benefits of nuts. At least some scientists agree with KIND, saying that nuts are "probably one of the healthiest choices you can make in a diet" and that FDA's guidelines are outdated in this respect.

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UPCOMING EVENTS

May 3–5, 2015: **Scott Edelstein** and **Alexis Gilroy** will speak at the American Telemedicine Association's Annual Meeting in a program titled *Telehealth Partnering in US & Abroad—A Look at Viable Strategies & Legal Considerations*. **Doug**

Senators Introduce Bill to Expand FDA Authority Over Cosmetics
Two senators recently introduced the Personal Care Products Safety Act, a bill that would significantly expand FDA's authority over cosmetics. Currently, FDA has the authority only to ask companies to voluntarily recall cosmetics, and the current scheme does not require manufacturers to disclose adverse health effects reporting by consumers.

Pearson, **Bruce Olcott**, and **Chris Mikson** will speak at a pre-conference session titled *Digital Health in Transition: Regulatory Insight for Product Developers*.

RELATED PRACTICES

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Senators Dianne Feinstein of California and Susan Collins of Maine are promoting the proposed bill as a measure to "protect consumers and streamline industry compliance" by strengthening FDA's authority over cosmetics. Senator Feinstein's press release further justifies the bill by saying that "[c]onsumer and health advocates are concerned about the use and concentration of some chemicals in personal care products," such as formaldehyde and propyl paraben.

Among other things, the proposed legislation would require FDA to evaluate a minimum of five ingredients per year to determine their safety and appropriate use and establish a review process to provide companies with clear guidance regarding the permissibility of certain chemicals, appropriate concentration levels, and consumer warnings. The proposed bill would also require companies to report "serious" adverse health effects (e.g., death, life-threatening experience, inpatient hospitalization, etc.) reported by consumers and would give FDA authority to force recalls.

FDA Issues New Recommendations on Fluoride Limits in Bottled Water
Earlier this week, FDA issued a letter to industry recommending that bottled water manufacturers, distributors, and importers limit the amount of fluoride they add to bottled water to no more than 0.7 milligrams per liter. The recommendations are in concert with a new Public Health Service ("PHS") recommendation for fluoride levels in community water systems. The PHS recommendation replaces previous ones permitting a higher level of fluoride. FDA intends to revise its current regulation establishing the quality standard for fluoride added to bottled water to reflect the new PHS limits.

Environmental Groups Challenge USDA Organic Compost Rule for Failure to Follow Notice and Comment Procedures
Three environmental groups recently sued USDA, alleging it failed to provide notice or seek public comment over a decision to allow organic food producers to use compost materials treated with synthetic pesticides. In July 2011, USDA implemented the Allowance of Green Waste and Organic Production Systems guidance, allowing National Organic Program certifying agents and certified and exempt organic producers to use composted plant and animal materials, which may be treated with synthetic pesticides, as long as it is not directly applied or contributes to contamination of crops, soils, or water. The Center for Food Safety, the Center for Environmental Health, and Beyond Pesticides are asking the court to annul the guidance and order USDA to follow formal rulemaking procedures asserting that the process is required. The environmental groups argue USDA's rule creates a new loophole for pesticides and "consumers want healthier choices and have a right to expect that the organic label insures that organic food was produced without harmful pesticides."

Vermont AG Formally Adopts GMO Labeling Rule
Last week, Vermont's Attorney General ("AG") formally adopted the Vermont state law making the state the nation's first to require labeling of genetically modified ("GM") food. Although Maine and Connecticut have also passed laws requiring such labeling, they will not go into effect until certain other states pass labeling laws for GM foods. At least 25 other states have considered similar legislation.

As reported previously in a Jones Day *Update*, Vermont's labeling law has already been challenged in federal court by the Grocery Manufacturers Association ("GMA") and other industry groups, alleging that the Vermont law impermissibly regulates nationwide

interstate commerce and offers no health or safety benefits to consumers. On April 27, 2015, the Vermont district court ruled against GMA, refusing to block the law from going into effect on July 1, 2016. The judge did, however, partially deny Vermont's motion to dismiss, allowing some of industry's claims against the state to proceed.

FDA Seeks Public Comment on Risk Assessment of Drug Residues in Milk, Milk Products
FDA is asking for public comment on a risk assessment it conducted of drug residues in milk and milk products. The risk assessment was conducted as part of the agency's effort to improve its regulatory system for milk and milk products. The risk assessment considered a wide range of data and information and reviewed four overarching criteria that factored into the drug's ranking, including the likelihood that the drug will be administered to lactating dairy cows, the likelihood that drug residues would be present in bulk milk, the relative extent of human exposure to the drug residue, and the potential for health hazards from the drug residue. FDA is particularly interested in comments on its ranking model approach, including the specific criteria, scoring, and weighting scheme; the assumptions and scientific data used to inform how the animal drugs were scored in the model; the selection of animal drugs evaluated; and the clarity and transparency of the risk assessment. FDA is accepting comments beginning April 30, 2015.

Commission Proposal Would Allow EU Member States to Ban GMOs
The European Commission ("EC") recently proposed amending a current regulation to allow European Union ("EU") Member States to decide whether to restrict or prohibit the use of EU-authorized genetically modified organisms ("GMOs") in their territory. Under the proposed regulation, an EU Member State could ban the use of GMOs that have received an authorization within the Community. It will be up to each Member State wanting to make use of this "opt-out" to justify the restriction or ban on a case-by-case basis, taking into account the GMO in question, the type of measure envisaged, and the specific circumstances at national or regional level that justify such an opt-out on the basis of "overriding reasons of public interest." The proposal, which has been opposed by EU food processors, farmers, and environmental groups, as well as the United States and other GM crop exporters, must be approved by EU Member States and the European Parliament before becoming law.

Other News
Chipotle to Stop Using GM Ingredients

U.S. Dolphin-Safe Labels Violate International Trade Laws, Says WTO

Wineries Face Class Action Over Arsenic Content

EFSA Publishes Annual Report on 2014 Activities

EFSA's Scientific Cooperation Report Highlights National Networking

EFSA Confirms Panel's Conclusions of No Cause–Effect Relationship Between Carbohydrate Consumption and Maintenance of Physical Performance

Regulatory Updates

APHIS Announces Meeting to Discuss Matters of Animal Health
In the April 14, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") announced a public meeting of the Secretary's Advisory Committee to discuss matters of animal health. Topics for discussion include a follow-up on antimicrobial resistance, mitigations, and USDA's action plan; a comprehensive discussion on porcine epidemic diarrhea; a follow-on discussion of foot-and-mouth disease; USDA draft framework for emerging diseases; proposed national list of reportable animal diseases; and discussions of avian influenza and the bovine tuberculosis program. ***The meeting will be held in Riverdale, Maryland on April 28–29, 2015***.

FDA Announces Petition to Amend Color Additive Regulations

In the April 22, 2015, *Federal Register*, FDA announced a petition to amend color additive regulations to allow for the safe use of a mica-based pearlescent pigment in certain distilled spirits.

APHIS Gives Notice of Availability of Environmental Assessment for Field Testing of Two Marek's Disease Vaccines
In the April 14, 2015, *Federal Register*, here and here, USDA's APHIS advised the public that it has prepared environmental assessments concerning authorization to ship and field test an unlicensed Marek's disease–Newcastle disease vaccine, serotype 3, live Marek's disease vector, and an unlicensed Marek's disease vaccine, serotype 1, live virus. The serotype 3 vaccine is intended for use in healthy 18-day-old or older embryonated eggs or day-old chickens to aid in the prevention of Marek's and Newcastle disease, viral diseases of poultry, while the serotype 1 is intended for use only in healthy day-old chickens to aid in the prevention of Marek's disease. The environmental assessments have determined that field testing these veterinary vaccines will not have a significant impact on the quality of the human environment. Accordingly, APHIS intends to authorize shipment of these vaccines for field testing. ***Comments are due May 14, 2015***.

NASS Announces Discontinuation of the Prices Paid Data Annual Publication
In the April 16, 2015, *Federal Register*, the National Agricultural Statistics Service ("NASS") announced its intention to immediately discontinue the publication of annual prices paid data. The data included prices paid for fuels, feed, seeds, fertilizer, machinery, and chemicals, which were published each year in the April Agricultural Prices Report. NASS will continue to collect data on prices paid by farmers and use the data to generate monthly indexes published in the monthly Prices Report.

USDA Announces Interim Rule Amending Conservation Compliance Requirements for Eligibility of USDA Benefits
In the April 23, 2015, *Federal Register*, USDA announced an interim rule amending regulations that define the conservation compliance requirements participants in USDA programs must meet to be eligible for certain USDA benefits, which include marketing assistance loans, farm storage facility loans, and payments under commodity, disaster, and conservation programs. Among other things, the rule amends the regulations to implement various 2014 Farm Bill provisions relating to wetlands. ***The rule was effective as of April 24, 2015; comments are due June 23, 2015***.

Other USDA Announcements
• Federal Crop Insurance Corporation Finalizes Common Crop Insurance Regulations and Macadamia Tree Crop and Macadamia Nut Crop Insurance Provisions
• Agricultural Marketing Service ("AMS") Issues Final Rule Relaxing Minimum Quantity Exception of Marketing Order Regulating Irish Potatoes in Colorado
• AMS Issues Proposed Rule to Implement Recommendation on Determination of Sales History Provisions Prescribed Under Cranberry Marketing Order
• AMS Issues Referendum Order to Determine Continuance of Marketing Order Regulating Handling of Cranberries Grown in Designated Areas
• AMS Issues Final Rule to Amend Honey Packers and Importers Research, Promotion, Consumer Education, and Information Order on Honey Assessment Rate
• AMS Adopts Interim Rule as Final Rule Changing Maturity Requirements of Florida Avocado Marketing Order
• APHIS Issues Final Rules to Allow Importation into U.S. of Fresh Apples from China, Fresh Peppers from Peru and Ecuador, Papayas from Peru, and Fresh Andean Blackberry and Raspberry Fruit from Ecuador
• APHIS Announces Availability of Treatment Evaluation Document Describing Revised Hot Water Treatment for Mango Commodities

USDA Announced the Following Requests for Information
• Noninsured Disaster Assistance Program
• FNS Generic Clearance for Pre-Testing, Pilot, and Field Testing Studies

USDA Announced Its Intent to Revise, Renew, and/or Extend the Following Information Collections

• Field Crops Production
• Document Delivery Services

FDA Announced the Following Information Collections Have Been Submitted to OMB
• Food and Cosmetic Export Certificate Application Process

European Regulatory Updates

EFSA Publishes Report Chemicals in Food
The European Food Safety Agency ("EFSA") has published a report targeting its data collection activities regarding the occurrence of chemicals in food. The purpose of the report is to give nonspecialists a balanced view of the findings of annual EU-wide monitoring of chemical levels in food. The report aims to provide certain context that is sometimes lacking when the media reports examples of chemicals detected in food.

EFSA to Hold Workshop on Allergenicity Assessment of GM Plants
EFSA has announced it will hold a workshop on June 17, 2015, in Brussels aimed at giving stakeholders the chance to shape EFSA's guidance on the allergenicity assessment of GM plans. The purpose of the event is for EFSA to gather relevant information and insights from stakeholders for the development of the guidance prior to its drafting. Interested participants from Member States, international partners, academia, NGOs, and industry can register online by May 6, 2015.

German Court Refers Question on Nutrition and Health Claims Made on Foods to the ECJ
A German court asked the European Court of Justice ("ECJ") whether Regulation (EC) No 1924/2006 of the European Parliament and of the Council of December 20, 2006, on nutrition and health claims made on foods should be interpreted to also apply to nutrition and health claims made in commercial communications in advertisements for foods delivered to the final consumer if the commercial communication or advertisement is addressed exclusively to the professional sector.

Council of European Union Appoints New EFSA Management Board Member
The Council of the European Union has appointed Michael Winter to the Management Board of EFSA. Winter, who works at the German Federal Ministry of Food and Agriculture, replaces Valérie Baduel, who resigned from the Board last year. Winter's mandate begins on May 1, 2015.

Upcoming Meetings, Workshops, and Conferences

Public Meeting to Discuss 38th Session of Codex Alimentarius Commission, **June 17, 2015**, in Washington, D.C.

EFSA Workshop on Allergenicity Assessment of GM Plants, **June 17, 2015**, in Brussels, Belgium.

FDA and AFDO Conference titled *In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation*, **June 20–24, 2015**, in Indianapolis, IN.

EFSA's 2nd Scientific Conference, **October 14, 2015**, in Milan, Italy.

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