Jones Day | Food, Dietary Supplement & Cosmetics Regulatory Update | Issue 1 | March 10, 2014

Top Stories

FDA Proposes Far-Reaching Changes to Nutrition Facts Panel
In a pair of Proposed Rules published in Monday's Federal Register, FDA proposed to significantly revamp how nutrition information is presented on packaged foods, including bolder calorie counts and a separate line item for the amount of sugar that is added to a product. FDA also proposes to change serving sizes to reflect updated data on what Americans actually eat, the practical effect of which would be increased amounts of calories, fat, sugar, and other nutrients—in some cases even doubling these amounts—on many product labels. Stakeholders must comment by June 2. Jones Day's *Commentary* on the proposed rules is available here.

FDA Settles with Food Safety Advocates to Complete Food Safety Modernization Act ("FSMA") by 2016
To settle a lawsuit brought by the Center for Food Safety over missed statutory deadlines, FDA agreed to finalize the seven major FSMA regulations by 2016, beginning with the rules for preventive controls and produce safety, scheduled to be finalized by August 2014 and the months following, respectively. The consent agreement was filed in a Federal District Court in California.

FDA Proposes Draft Methodological Approach to Identifying High-Risk Foods under FSMA
FSMA requires FDA to designate high-risk foods for which additional recordkeeping requirements are needed to enable fast and effective tracking of foods during a foodborne illness outbreak or other event. As the first step toward meeting that requirement, in February, FDA announced its plans to publish a list of the designated high-risk foods either before or at the same time that the agency issues a proposed rule to establish the recordkeeping requirements for such foods. The comment period ends on April 7, and additional information is available in the *Federal Register* notice.

Harvard School of Public Health Highlights Cosmetic Ingredient Safety
Continuing an ongoing debate on the safety of cosmetic ingredients, Harvard School of Public Health hosted a talk on "Harmful and Untested Chemicals in Everyday Products." The speaker noted that increased rates of certain illnesses have been linked to chemical exposure and that many chemical ingredients in cosmetics have never been tested. On a related note, FDA also published to its website the report of the International Cooperation on Cosmetics Regulation working group on Safety Approaches to Nanomaterials in Cosmetics.

Food Industry Forms Group to Stop Labeling of Genetically Engineered Foods
Groups representing seed, grain, and packaged-food companies formed the Coalition for Safe Affordable Food in an attempt to prevent states from requiring labels on products containing GMOs. The 29-member coalition includes companies such as PepsiCo Inc., the world's largest snack food maker, and Monsanto Co., the biggest seed company. The coalition is seeking to prevent state initiatives requiring that genetically engineered foods to be labeled, such as those already approved by voters in Connecticut and Maine, and has urged Congress to pass a bill preempting such laws.

FDA Reopens Comment Period on Draft Industry Guidance on Evaporated Cane Juice as a Food-Labeling Term
FDA reopened the comment period on its draft guidance for industry on declaring "evaporated cane juice" as an ingredient on food labels. The agency originally published and accepted comments on the guidance in fall 2009. The draft guidance advises industry that sweeteners derived from cane syrup should not be listed as evaporated cane juice because the sweetener is not a juice as defined by federal regulations. Stakeholders must submit comments by May 5.

2014 Farm Bill Becomes Law
The long-awaited Farm Bill finally became law in February. The Act extends funding for organic production and market initiatives as well as food safety initiatives. Other high-profile issues in the law include cuts to the Supplemental Nutrition Assistance Program, commonly known as "food stamps," the end of direct payment crop subsidies, and efforts to increase coordination between FDA and USDA food-inspection activities. PICA (the Protect Interstate Commerce Act, aka the King amendment), a proposal forbidding states from imposing their own higher standards or conditions on food produced or manufactured in another state, did not make it

into the law. The law does not include any significant changes to country-of-origin labeling requirements.

Other News
FDA Announces Updated Foods "Popular Topics" webpage.

FDA Issues Annual Report to Congress on the Use of Mandatory Recall Authority.

Michael R. Taylor testifies before House on Implementing the FDA Food Safety Modernization Act.

FDA Announces Updated FDA requirements for infant formula.

Food Safety News: Three-Quarters of Americans Want More Government Food Safety Oversight According to Harris Poll.

Food Safety Magazine: Indian Health Minister Mute on Food Safety in Talks with FDA Commissioner.

NYT: Antibiotics in Animals Tied to Risk of Human Infection.

NYT: Modified Corn a Step Closer to Approval in Europe.

Regulatory Updates

FDA Announces Revision of the Nutrition and Supplemental Facts Labels
In the March 3 *Federal Register*, FDA proposed 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. In the same day's *Federal Register*, FDA also proposed amending the definition of a single-serving container and added several products and food product categories to the reference amounts customarily consumed per eating occasion. (See news section above for additional information on the pair of Proposed Rules). In a related notice, FDA withdrew pending proposed rules on hard candies and breath mints to reflect the latest proposal. ***Comments due June 2***.

FDA Reopens Comment Period on Draft Industry Guidance on Evaporated Cane Juice as a Food-Labeling Term
In the March 5 *Federal Register*, FDA reopened the comment period on its draft guidance for industry on declaring "evaporated cane juice" as an ingredient on food labels. (See news section above for additional information on the draft guidance.) The draft guidance advises industry that sweeteners derived from cane syrup should not be listed as evaporated cane juice because the sweetener is not a juice as defined by federal regulations. ***Comments due May 5***.

USDA's Food and Nutrition Service Promulgates Final Rule Revising WIC Food Packages
In the March 4 *Federal Register*, FNS announced finalization of its rule revising WIC food packages to bring them more in line with updated nutrition science and the infant feeding practice guidelines of the American Academy of Pediatrics. The rule also seeks to promote and support more effectively the establishment of successful long-term breastfeeding and provide WIC participants with a wider variety of food. Another major goal of the revision was to provide state agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences. The final rule becomes effective on May 5 and is the first comprehensive revision to WIC food packages since 1980.

USDA's Animal and Plant Health Inspection Service Extends Comment Period on Environmental Impact Statement for Determination of Nonregulated Status of Herbicide-Resistant Corn and Soybeans
In the February 25 *Federal Register*, APHIS announced that it would extend the comment period for a draft environmental impact statement on environmental impacts that may result from the potential approval of petitions seeking a determination of nonregulated status of three cultivars of herbicide-resistant corn and soybeans produced by Dow AgroSciences LLC. ***Comments due March 11.***

USDA's Animal Plant Health Inspection Service ("APHIS") Issues Preliminary Finding of No Significant Impact for the Determination of Nonregulated Status of Soybeans that are Genetically Engineered for Insect Resistance
In the March 3 *Federal Register*, APHIS advised the public that it finds no significant environmental impact for the preliminary determination of nonregulated status, as requested by Dow AgroSciences LLC in its petition for nonregulation for its genetically engineered soybean (*Glycine max*). The soybean is designed to resist certain pests and herbicides.

USDA's Food and Nutrition Service Issues Proposed Rule on Local School Wellness Policy Implementation Under the Healthy, Hunger-Free Kids Act of 2010

In the February 26 *Federal Register*, FNS proposed a rule to require all local educational agencies participating in the National School Lunch Program and/or the School Breakfast Program to meet expanded local school wellness policy requirements consistent with the new requirements set forth in section 204 of the Healthy, Hunger-Free Kids Act of 2010. This proposed rule would establish the framework for the content of the local school wellness policies, ensure stakeholder participation in the development of such policies, and require periodic assessment of compliance and reporting on the progress toward achieving the goals of the local school wellness policy. This proposed rule would also require local educational agencies, as part of the local school wellness policy, to implement policies for the marketing of foods and beverages on the school campus during the school day consistent with nutrition standards for Smart Snacks. Additionally, this proposed rule would require each local educational agency to make information about local school wellness policy implementation for all participating schools available to the public on a periodic basis. ***Comments due April 28.***

USDA's Animal and Plant Health Inspection Service Reopens Comment Period on Proposed Rule Allowing Importation of Fresh Beef from a Region in Brazil
In the February 27 *Federal Register*, APHIS announced an extension of the comment period for the proposed rule on beef importation from Brazil, which appeared in the *Federal Register* on December 23. ***Comments due April 22.***

HHS and FDA Deny Hearings on Final Rule Regarding Irradiation in the Production, Processing, and Handling of Food
In the February 25 *Federal Register*, FDA and HHS responded to objections and denied requests for a hearing on the final rule that appeared in the *Federal Register* of August 22, 2008 amending the food additive regulations to provide for the safe use of ionizing radiation for control of food-borne pathogens and extension of shelf life in fresh iceberg lettuce and fresh spinach.

USDA's Food Safety Inspection Service ("FSIS") Discontinues Qualitative (30 mL) Campylobacter Analysis for Young Chickens
In the February 21 *Federal Register*, FSIS announced that it would discontinue the 30-mL qualitative analysis for *Campylobacter* organisms in young chickens. FSIS had already suspended this analysis as of June 3, 2013, and recent analysis suggests that the performance standard based on a 1-mL sample is sufficiently sensitive.

APHIS Solicits Members for General Conference Committee of the National Poultry Improvement Plan
In the February 24 *Federal Register*, USDA announced it is soliciting nominations for the election of regional membership, a member-at-large, and alternates to the General Conference Committee of the National Poultry Improvement Plan. ***Consideration will be given to nominations received on or before May 9.***

Agricultural Marketing Service Announces Changes in Size and Grade Requirements
Kiwifruit Grown in California and Imported Kiwifruit; Relaxation of Minimum Grade Requirement

Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas; Change in Size and Grade Requirements for Grapefruit

Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas and Imported Oranges; Change in Size Requirements for Oranges

FDA published the following *Federal Register* Notices Regarding Agency Information Collection Activities:

Opportunity for comment on submission for OMB review and clearance of *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements* (comments due March 27).

Opportunity for Comment on proposed collection of information on Animal Feed Network (Pet Event Tracking Network and LivestockNet)—State, Federal Cooperation to Prevent Spread of Pet Food and Animal Feed Related Diseases (comments due March 27).

Opportunity for comment on proposed collection of information on Information from United States Firms and Processors that Export to the European Community (comments due March 31).

Opportunity to comment on proposed collection of information on Establishing and Maintaining Lists of United States Milk Product Manufacturers/Processors with Interest in Exporting (comments due April 21).

FDA announces OMB approval of information collection on Animal Feed Regulatory Program Standards.

Request for extension of approval of information collection on Importation of Hass Avocados From Michoacan, Mexico (comments due April 22).

Request for extension of approval of information collection on Plants for Planting Regulations (comments due April 22).

Opportunity to comment on proposed information collection on Animal Drug User Fee Act Waivers and Reductions (comments due April 28).

Opportunity to comment on request for revision to and extension of approval of information collection Animal Disease Traceability (comments due April 28).

Opportunity to comment on request for extension of approved information collection for Data Collection for Container Availability (comments due April 29).

Upcoming Meetings, Workshops, and Conferences

Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Additional Public Meeting on the Proposed Rule). **March 13** in Anaheim, CA.

Third 2015 Dietary Guidelines Advisory Committee Meeting. **March 14** by webcast.

Food Safety Summit. **April 8–10** in Baltimore, MD.

Enforcement Updates

Recent Product Recalls

Recent FDA food product recalls have primarily been for undeclared allergens in a variety of food products. Other recalls have been for compromised product packaging and bacterial contamination, specifically *Listeria.*

The USDA's Food Safety and Inspection Service similarly issued several recall notices for undeclared allergens and possible bacterial contamination. Notably, in February, 8.7 million pounds of beef were recalled because it came from "diseased and unsound animals" that were not inspected according to the regulations. (This announcement is a significant expansion of the recall announced in mid-January by Rancho Feeding Corporation and appears to be a change in policy by FSIS.)

Click here for a complete listing of FDA Recalls.

Recent Warning Letters

Several warning letters were issued in February, fewer than usual. One cited adulteration of a medicated feed and the other involved unsanitary conditions.

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