Jones Day | Food, Dietary Supplement & Cosmetics Regulatory Update Issue 13 | September 2014

Top Stories

FDA, Industry Group Announce Initiatives to Revamp Safety Assessments of Food Ingredients and Other Products
Last month, FDA and the Grocery Manufacturers Association ("GMA") separately announced new initiatives aimed at improving industry and governmental safety assessments of food and other regulated products—all at a time when the food additive market is experiencing significant growth.

According to its press release, GMA plans to develop a private database to collect and analyze information on food additives and scientific findings commonly used by food companies in "generally recognized as safe" ("GRAS") determinations. Although the project may take several years to complete, GMA will grant access to FDA as an effort to enhance the agency's information on ingredients and promote national standards on additive safety.

Separately, but in a related action, FDA announced the results of an internal review assessing the agency's approach to evaluating harmful chemical effects in various regulated products. Initiated in 2012 by the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, the review focused on FDA's policies and practices for assessing chemical safety in food, dietary supplements, cosmetics, and animal feed. Based on the findings, FDA plans to update the Toxicological Principles for the Safety Assessment of Food Ingredients (or "Redbook") and promote more consistent methodologies within and among the Centers. The agency will conduct similar reviews of its nutrition and microbiological laboratory programs.

USDA Issues Final Rule on Modern Poultry Inspection
Late last month, USDA issued a final rule to establish a new inspection system for young chicken and all turkey slaughter establishments, representing the first major overhaul of poultry inspections since 1957. The policies include an optional New Poultry Inspection System ("NPIS"), which allows for more offline inspections and sets new maximum line processing speeds. Establishments may elect to adopt NPIS by February 23, 2015; slaughterhouses that forgo this option will continue to operate under a current inspection

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Resources

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system. Other aspects of the final rule, such as pathogen prevention rules for developing a microbiological sampling plan, are mandatory for all establishments. Another provision will allow establishments to set their own performance-based chilling procedures, as long as such procedures are validated according to the agency's validation rules. USDA's final rule responds to an executive order instructing all federal agencies to look for ways to promote regulatory efficiency.

- Jones Day's FDA Regulatory & Compliance Counseling Practice
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

FDA Warns Consumers: Dietary Supplements Can't Treat Concussions
FDA recently issued a consumer alert advising readers not to be tricked by dietary supplement products that claim to treat concussions and other brain trauma injuries. The alert targets misleading claims by some manufacturers that taking a particular dietary supplement will protect one from brain damage or lead to faster healing after a concussion. FDA said such claims are untested and unproven, and the agency has taken several actions recently to enforce its policies in this area. The consumer alert coincides with the back-to-school period, when many student athletic programs and recreational sports are set to resume, and reflects continued efforts by regulators and industry to bring attention to sports-related concussions.

USDA Takes Steps to Assess Need for Honey Identity Standard
USDA has started soliciting comments on possible plans to adopt a standard of identity for honey. Under the Agricultural Act of 2014, the agency must develop a report to assess whether a federal standard would be in the interest of consumers, the honey industry, and U.S. agriculture. In addition to addressing new comments, the law requires USDA to consider relevant citizen petitions filed with FDA in 2006, which were denied when FDA concluded a standard was not necessary. There are already several standards governing the inspection, grading, and sale of honey, including FDA labeling requirements summarized in a draft guidance earlier this year. Supporters of an identity standard say it would help prevent fake honey from entering the U.S. market. These developments also come at a time when a historic drought in California has reduced honey production and resulted in higher prices for consumers. Comments on USDA's honey identity assessment report are due September 19, 2014.

Other News
USDA Reopens Chinese Market Access for California Citrus

NIH Review Finds Ovarian Toxicity Risks Associated with BPA

Using Social Media Tip, USDA Seizes 1,200 Illegal Giant Snails

Congressional Dems Express Concerns Over FSMA Funding, Discourage User Fees

Maine Regulators: Recalled Beef Posed Risk of Transmitting BSE

Regulatory Updates

USDA Issues Final Rule on Modern Poultry Inspection
In the August 21, 2014, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") issued a final rule amending the poultry products inspection regulations to establish a new inspection system for young chicken and all turkey slaughter establishments. All such establishments have until February 23, 2015, to notify their District Office in writing of their intent to operate under the NPIS. Establishments that do not provide such written notice will be deemed to have chosen to continue operating under whichever inspection system they are currently regulated. With the goal of making the inspection process more efficient, the NPIS has four key elements: (i) requiring establishment personnel to sort carcasses and remove unacceptable carcasses and parts before the birds are presented to the FSIS inspector; (ii) shifting agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which will allow for one offline verification inspector per line per shift and will reduce the number of online inspectors to one; (iii) replacing the Finished Product Standards; and (iv) requiring young chicken slaughter establishments to operate at a maximum line speed of 140 birds per minute, provided that they maintain process control.

USDA Issues Proposed Rule on Importation of Beef from Northern Argentina
In the August 29, 2014, *Federal Register*, USDA proposed an amendment to the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from a certain region of Argentina. Based on a recent risk assessment, the agency has determined such beef can be safely imported, provided certain conditions are met. ***Comments due October 28, 2014***.

USDA Issues Final Rule on Margin Protection Program for Dairy and Dairy Product Donation Program
In the August 29, 2014, *Federal Register*, USDA issued a final rule implementing regulations for the Margin Protection Program for Dairy ("MPP-Dairy") and the Dairy Product Donation Program. MPP-Dairy provides dairy producers with risk management coverage that will pay producers when the difference between the price of milk and the cost of feed falls below a certain level. MPP-Dairy provides basic catastrophic-level coverage for an administrative fee and greater coverage for a premium in addition to the administrative fee. Authorized by the Agricultural Act of 2014, the rule specifies the eligibility requirements and payment formulas for the programs and is effective immediately.

USDA Proposes Allowing Importation of Certain Fresh Citrus Fruits from South Africa and China
In the August 28, 2014, *Federal Register*, USDA proposed two rules to amend the fruits and vegetables regulations to allow the importation of several varieties of fresh citrus fruit into the continental United States from South Africa and from China, as long as the shipments meet certain conditions outlined in the proposed regulations. ***Comments on both proposals due October 27, 2014***.

USDA Announces Comment Period for Report on Standard of Identity for Honey
In the August 20, 2014, *Federal Register*, USDA requested public comments for inclusion in a report assessing whether a federal standard of identity for honey would be in the interest of consumers, the honey industry, and U.S. agriculture. In addition to addressing any responsive comments, the Agriculture Act of 2014 requires USDA to consider similar citizen petitions submitted to FDA in 2006 but subsequently denied by that agency. ***Comments due September 19, 2014***.

FDA Announces Withdrawal of Food Additive Petitions for Infant Formula
In the September 2, 2014, *Federal Register*, FDA announced the withdrawal of a food additive petition (FAP 3A4798) proposing the food additive regulations be amended to prohibit the use of carrageenan and salts of carrageenan in infant formula. The petition is withdrawn without prejudice, meaning it could be resubmitted in a future filing. In the same notice, FDA also announced the withdrawal of a citizen petition requesting the GRAS regulations be amended to prohibit the use of Chondrus extract (carrageenan) in infant formula.

USDA Issues Final Rule Exempting Bulk Apple Shipments to Canada from Minimum Requirements and Inspection
In the August 25, 2014, *Federal Register*, USDA adopted as a final rule, without change, an interim rule exempting bulk shipments of apples (more than 100 pounds) to Canada from the minimum requirements and inspection provisions of the Export Apple Act and establishing a definition for bulk containers. The final rule implements changes ordered by the Agricultural Act of 2014. The rule was effective August 26, 2014.

FDA Publishes Notice of Petition Filed for Zinc Additive in Chicken Feed
In the August 21, 2014, *Federal Register*, FDA announced that a mineral additive manufacturer has filed a petition proposing the food additive regulations be amended to provide for the safe use of zinc L-selenomethionine as a source of selenium in complete feed for broiler chickens. ***Comments due September 22, 2014***.

FDA Solicits Nominations for Consumer Representatives to Advisory Committees
In the August 20, 2014, *Federal Register*, FDA called for consumer organizations interested in participating in the selection of consumer representatives to serve on its advisory committees or panels to notify FDA in writing by September 19, 2014. FDA also called for nominations for consumer representatives to serve on advisory committees or panels with vacancies. ***Nominations due September 19, 2014***.

FDA INFORMATION COLLECTION ACTIVITIES

FDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Temporary Marketing Permit Applications (*comments due September 19, 2014*)

FDA Announces the Following Information Collections Have Been Submitted to OMB
Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations (*comments due to OMB September 22, 2014*)

Third Party Disclosure and Recordkeeping Requirements for Reportable Food (*comments due to OMB September 24, 2014*)

USDA INFORMATION COLLECTION ACTIVITIES

USDA Announces the Opportunity to Comment on the Following Proposed Information Collections
User Access Request Form FNS-674 (*comments due October 28, 2014*)

USDA Announces the Opportunity to Comment on the Following Request for Revisions to and/or Extensions of Approval of Information Collections
Organic Survey (*comments due October 20, 2014*)

Regulations Governing the Inspection and Grading of Manufactured or Processed Dairy Products—Record Keeping (*comments due October 24, 2014*)

Importation of Clementines from Spain (*comments due October 27, 2014*)

Infectious Salmon Anemia; Payment of Indemnity (*comments due October 27, 2014*)

Importation of Gypsy Moth Host Material from Canada (*comments due October 27, 2014*)

Application for Inspection, Accreditation of Laboratories, and Exemptions (*comments due November 3, 2014*)

Public Health Information System (*comments due November 3, 2014*)

USDA Announces the Following Information Collections Have Been Submitted to OMB
Gypsy Moth Identification Worksheet (*comments due to OMB September 18, 2014*)

Livestock Slaughter (*comments due to OMB September 29, 2014*)

Supplemental Nutrition Assistance Program Education Connection Resource Sharing Form (*comments due to OMB October 2, 2014*)

County Committee Election (*comments due to OMB October 2, 2014*)

Black Stem Rust; Identification Requirements and Addition of Rust-Resistant Varieties (*comments due October 2, 2014*)

Other USDA Announcements
USDA Announces Opportunity for Designation of Official Agencies Serving the Montgomery, AL; Saginaw, TX; Essex, IL; Savage, MN; and Olympia, WA Areas (*comments due September 25, 2014*)

USDA Issues Interim Rule on Decreased Assessment Rate for Domestic Dates Produced or Packed in Riverside County, CA (*comments due October 27, 2014*)

Determination of Pest-Free Areas in Australia

Notice of Determination of the Foot-and-Mouth Disease and Rinderpest Status of a Region of

Patagonia, Argentina

Availability of Preliminary Finding of No Significant Impact and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Soybean Genetically Engineered for Resistance to Lepidopteran Insects

Availability of an Environmental Assessment for the Field Release of Genetically Engineered Diamondback Moths

USDA Adopts Final Rule Modifying Handling Regulations for Yellow Fleshed and White Types of Potatoes Under Washington Potato Marketing Order

Upcoming Meetings, Workshops, and Conferences

Fifth 2015 Dietary Guidelines Advisory Committee Meeting, **September 16–17, 2014**, via Internet webcast

Meeting of the Codex Committee on Food Labeling, **September 23, 2014**, in Washington, D.C.

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

FDA Food Advisory Committee Meeting, **December 16–17, 2014**, in Washington, D.C.

Enforcement Updates

Recent Product Recalls
Recent food recalls involved microbial contaminations, undeclared ingredients, and one product with questionable packaging seals. One manufacturer recalled multiple brands of peanut and almond butters due to potential *Salmonella* contamination. A brand of parmesan cheese was also recalled for *Salmonella* concerns, while another cheese product was called back because a supplier did not properly store ingredients according to the manufacturer's temperature standards. Two companies also recalled breaded chicken products and chicken Caesar salad kits for possible *Listeria* contamination.

Additionally, manufacturers recalled several food products because the products contained undeclared allergens. Another company recalled certain lots of two canned vegetable products because the cans may not have been properly sealed to ensure safety.

As FDA continues to test dietary supplements for illegal ingredients, another appetite-control supplement was recalled last month for containing DMMA.

Finally, two adult dog food products were recalled for presence of foreign materials.

For a complete list of product recalls, click here for FDA-regulated products, and here for USDA-regulated products.

Recent Warning Letters
Recent warnings since the last Update include notices to five dairy farms for selling cattle adulterated with illegal drug residue and a warning letter to a lobster-processing facility for failing to comply with hazard analysis and critical control points regulations.

FDA also posted warning letters to several dietary supplement manufacturers. The agency cited a private label manufacturer for violating current good manufacturing practice requirements and marketing misbranded products, in part because the labels of several products lacked the required term "dietary supplement." FDA warned two other dietary supplement manufacturers for marketing unapproved drugs because their products promote therapeutic claims.

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