JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
Issue 14 | September 2014 JONES DAY

Top Stories

FDA Deputy Commissioner: Agency Focusing on Coordinated Food Safety and Specialized Inspectors

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To facilitate these efforts, FDA is transitioning away from general inspectors, who were traditionally engaged by regional field offices to review all types of regulated products—food, drugs, medical devices, dietary supplements, and cosmetics. Instead, FDA will use specialized food inspectors who can develop expertise in a specific product category and better collaborate with scientists at FDA's Center for Food Safety and Applied Nutrition.

Read more below

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FDA Clarifies Policy on Artisanal Cheeses Following Media Coverage of Import Alert

In August 2014, FDA placed certain cheeses on import alert following bacterial test results that exceeded tolerance levels. Several prominent news outlets reported that the policy could effectively prohibit imports of cheeses such as Roquefort, Morbier, St. Nectaire, and Tomme de Savoie, whose recipes usually call for a special type of bacteria. FDA has since

issued an update on the status of artisanal cheese to clarify that these stories "have incorrectly indicated that the FDA is banning Roquefort and other cheeses."

The update explains that FDA placed the products on import alert after nine cheese producers tested above threshold levels for non-toxigenic *E. coli*, suggesting that their products were made in unsanitary conditions. Since then, FDA has been working with industry groups, and based on discussions regarding the process and safety measures in place during artisanal cheesemaking, the agency has "adjusted its criteria for taking regulatory action based on [these test results]." FDA simultaneously revised the import alert to account for these new criteria, removing six of the nine cheese producers. Recent correspondence with the American Cheese Society also indicates the agency is planning revisions to its Compliance Program Guidance for Domestic and Imported Cheese Products. Stakeholders may comment on the guidance at any time.

Groups Seek Rehearing in Second Circuit Case Challenging Livestock Antibiotic Policies
On September 8, 2014, the Natural Resources Defense Council ("NRDC") and other groups filed a petition in the U.S. Court of Appeals for the Second Circuit, requesting en banc review of a three-judge panel ruling that FDA is not required to ban certain antibiotics in livestock feed. The petition argues that the panel majority overlooked the significance of an administrative procedure that compels FDA to withdraw approval of livestock antibiotics. NRDC argues that "[b]y holding that FDA need not act on its findings that approved drug uses are not shown to be safe, the majority writes the withdrawal provision out of the Food and Drug Act." In 1977, FDA proposed a plan to withdraw certain feed antibiotics based on concerns that microbes would spread to humans because of animal antibiotic resistance. When FDA abandoned the plan in 2011, NRDC and others brought the instant litigation to demand enforcement of the original assessment. The plaintiffs prevailed at the trial level, but that decision was overturned in July by the Second Circuit panel.

Other News
Poultry Producer Reports Eliminating Use of Antibiotics in Hatcheries

Federal Court Issues Injunction Against Manufacturer to Stop Sale of Dietary Supplements

New Coalition Aims to Coordinate Advocacy Efforts to Reduce Antimicrobial Resistance

Chinese Authorities Arrest Six Over Expired Meat Incident

Regulatory Updates

FDA Plans to Evaluate Modifying Procedures for Combination Medicated Feeds
In the September 9, 2014, *Federal Register*, FDA announced it will evaluate the use of statutory revisions and other modifications to the existing procedures and requirements related to the approval of combination drug medicated feeds. Currently, the use of multiple new animal drugs in the same medicated feed requires an approved new animal drug application ("NADA") for each new drug in the combination and a separate approved NADA for the combination new animal drug itself. Through a performance goals letter authorized by the Animal Drug User Fee Amendments of 2013 ("ADUFA III"), FDA and industry participants agreed to explore potential changes to the approval process. ***Comments due September 9, 2015***.

FDA to Explore Expanding Conditional Approvals for New Animal Drugs
In the September 9, 2014, *Federal Register*, FDA announced it will explore using statutory changes to expand the use of conditional approval beyond new animal drugs intended for minor species or minor uses in major species. FDA is conducting this review pursuant to performance goals from ADUFA III. ***Comments due March 9, 2015***.

USDA Proposes Performance Standard for Importing Fruits and Vegetables
In the September 9, 2014, *Federal Register*, USDA proposed a rule to amend its

regulations governing the importation of fruits and vegetables by broadening its existing performance standard to provide for approval of all new fruits and vegetables for importation into the United States, using a notice-based process and removing region- or commodity-specific requirements. The proposed rule also affects interstate movements of fruits and vegetables from Hawaii and the U.S. territories. ***Comments due November 10, 2014***.

FDA Approves Seven New Animal Drugs
In the September 8, 2014, *Federal Register*, FDA announced it has amended the animal drug regulations to reflect approvals for the following new animal drug applications: buprenorphine, carprofen, danofloxacin, follicle stimulating hormone, ractopamine, salinomycin, and tylosin.

FDA Rules Michigan Counties Free of Bovine Tuberculosis
In the September 10, 2014, *Federal Register*, USDA announced that several Michigan counties met the criteria for relieving certain restrictions on the interstate movement of cattle and bison from those areas. ***Comments due November 10, 2014***.

USDA Affirms Rule on Soybean Promotion
In the September 10, 2014, *Federal Register*, USDA affirmed its interim rule amending the procedures to request a referendum under the Soybean Checkoff Program, a federal program that invests collections from the prior season's profits in research and promotion efforts. The rule is effective as of September 11, 2014.

USDA Issues Final Rule on Importation of Litchi and Longan Fruit From Vietnam
In the September 4, 2014, *Federal Register*, USDA issued a final rule amending the fruits and vegetables regulations to allow the importation of litchi and longan fruit from Vietnam into the continental United States. Based on a recent risk assessment, the agency has determined such fruit can be safely imported provided certain conditions are met.

USDA Issues Proposed Rule to Consolidate and Update Farm Service Environmental Regulations
In the September 3, 2014, *Federal Register*, USDA's Farm Service Agency ("FSA") issued a proposed rule to consolidate, update, and amend its regulations implementing the National Environmental Policy Act of 1969 ("NEPA"). FSA's NEPA regulations have been in place since 1980. The proposed changes would address the increased scope of FSA programs and better align the agency's rules with the President's Council on Environmental Quality regulations and guidance on NEPA. ***Comments due December 2, 2014***.

FDA Information Collection Activities

Since the last *Update*, there have been no FDA information collectivities related to food, dietary supplements, or cosmetics.

USDA Information Collection Activities

USDA Announced the Opportunity to Comment on the Following Proposed Information Collections
Supplemental Nutrition Assistance Program Pre-Screening Tool (*comments due November 17, 2014*)

USDA Announced the Opportunity to Comment on the Following Request for Revisions to and/or Extensions of Approval of Information Collections
Control of Chronic Wasting Disease (*comments due November 3, 2014*)

Guidelines for the Transfer of Excess Computers or Other Technical Equipment Pursuant to Section 14220 of the 2008 Farm Bill (*comments due November 11, 2014*)

USDA Announced the Following Information Collections Have Been Submitted to

OMB
Application Package and Reporting Requirements for the Veterinary Medicine Loan Repayment Program (*comments due to OMB October 3, 2014*)

2014 Tenure, Ownership, and Transition of Agricultural Land (*comments due to OMB October 14, 2014*)

Supplemental Nutrition Assistance Program Case and Procedural Case Action Review Schedule (*comments due to OMB October 16, 2014*)

Other USDA Announcements
USDA Announces Change in Maturity Requirements for Avocados Grown in South Florida and Imported Avocados (*comments due November 17, 2014*)

USDA Announces Determination of Total Amounts of Fiscal Year 2015 WTO Tariff-Rate Quotas for Raw Cane Sugar and Certain Sugars, Syrups, and Molasses

Upcoming Meetings, Workshops, and Conferences

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

Meeting of the Council for Native American Farming and Ranching, September 25–26, 2014, in Washington, D.C.

Fruit and Vegetable Industry Advisory Committee Meeting, September 29–30, 2014, in Arlington, VA.

Meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses, October 28, 2014, College Park, MD.

Meeting of the Organic Standards Board, October 28–30, 2014, Louisville, KY.

FDA Risk Communications Advisory Committee Meeting, 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 undeclared allergens, microbial and foreign material contaminations, and choking hazards.

Ground black pepper products and a brand of salad kits were recalled by their manufacturers because of potential *Salmonella* contamination. Another company called back pasta sauces because of high risks of botulism, a potentially fatal foodborne illness. In addition, a manufacturer recalled some bite-sized snacks because they pose choking hazards to children, and another company recalled certain bagels after some packages were found containing tiny glass particles.

USDA posted information about recalls of certain beef jerky and sausage products due to undeclared allergens. Another company recalled raw chicken because of deviations in temperature during its processing.

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

Recent Warning Letters
Since the last *Update*, FDA posted warning letters to two canning companies for various

violations, including packaging food in insanitary conditions and failing to submit scheduled processes to FDA.

Five seafood processing facilities were cited for hazard analysis and critical control points violations. One of these, a noodle company, also failed to label artificial flavoring in its shrimp products.

In addition, FDA issued warning letters to two farms for illegal drug residue found in cows sold for slaughter.

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

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Taylor said this new approach will help inspectors develop an understanding of each company's "food-safety culture," or commitment to compliance, which will, in turn, inform how often FDA needs to return for additional assessments. Taylor acknowledged that farm monitoring will be done in collaboration with state departments of agriculture. One week following his speech, FDA announced a cooperative agreement with the National Association of State Departments of Agriculture to help plan and implement the national produce safety rule.

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Taylor noted that final rules on preventive controls, produce safety, and foreign suppliers are expected in 2015, but enforcement may still be as many as four years away. In the meantime, FDA will hold public meetings to discuss implementation.

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