Food, Dietary Supplement & Cosmetics Regulatory Update
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Top News

FDA Final Rule Aims to Reduce Antibiotic Use in Farm Animals
FDA issued a final rule last week, called the Veterinary Feed Directive ("VFD"), that reduces the amount of antibiotics used in animal production. As part of a broader attempt by the Obama administration to fight antibiotic-resistant bacteria, or so-called "superbugs," the VFD brings these drugs under the supervision of a licensed veterinarian to ensure the drugs are used only when needed for an animal's health. FDA's goal is to eliminate antibiotic use for production purposes (such as accelerating an animal's weight gain).

The final rule requires veterinarians to issue feed directives in the context of a valid veterinarian-client-patient relationship under the guidelines of the state where the veterinarian practices. States lacking VCPR requirements must follow federally defined VCPR standards.

According to Michael R. Taylor, FDA deputy commissioner for foods, "[t]he actions the FDA has taken to date represent important steps toward a fundamental change in how antimicrobials can be legally used in food-producing animals." FDA has issued a draft guidance in question-and-answer format to assist industry in interpreting and applying the VFD, which will go into effect October 1, 2015.

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The VFD is not the final step in FDA's attempts to change how antibiotics are used in food-producing animals. According to Taylor's recent blog post, FDA's next step is to obtain data on how medically important antibiotics are currently used on farms. In conjunction with USDA and the Centers for Disease Control and Prevention, FDA is currently evaluating how to obtain additional information on such things as the species, indication, dose, and duration of use "to better understand links between usage patterns and trends in antibiotic resistance." Some in the industry have already taken steps to reduce antibiotic use in their products. Over the past year, two major food companies have already announced they have pulled antibiotics from their chicken farms.

New FDA Program for Expedited Review and Import of Certain Foods
Last week, FDA announced a new voluntary, fee-based program called the Voluntary Qualified Importer Program ("VQIP") for the expedited review and importation of foods into the United States from importers with a proven food safety track record. The VQIP, which is required under the Food Safety Modernization Act ("FSMA"), will be available to importers who "achieve and maintain a high level of control over the safety and security of their supply chains." VQIP is designed to benefit industry and consumers, offering industry expedited entry for qualified imported foods and offering consumers enhanced protection by reallocating FDA resources for food imports more likely to pose a risk to public health. FDA has released a draft guidance on the new program, which, among other details, provides information on the benefits of VQIP for importers, eligibility criteria, and application instructions.

EPA Proposes Pesticide Restriction to Save Honeybees
The U.S. Environmental Protection Agency ("EPA") recently proposed a new measure aimed at protecting the declining bee population. The proposal would add restrictions on the use of acutely toxic pesticides during times when bees are most likely to be present. In effect, the proposed rule would create temporary pesticide-free zones when certain plants are in bloom and bees are trucked in to farms by professional beekeepers to pollinate the crops. Such bees constitute the majority of honeybees in the United States. Although the pesticide restrictions would apply to virtually all insecticides, they would affect only the property where bees are working, not neighboring land. In addition, the proposal would not apply to residential pesticide use or home beekeeping, but is instead restricted to farms where professional beekeepers bring in hives to help pollinate the crops. The proposal is part of the Obama administration's initiative to protect pollinators. Although the proposed rule would not eliminate pesticide exposure to honeybees, it would reduce the exposure.

House Passes Bill to Loosen Restrictions on Fishing
The House recently passed a bill to remove a 10-year timeframe for rebuilding depleted fish stocks and allow regional fishery managers to set annual local fishing levels while considering the economic needs of fishing communities. President Barack Obama, along with other Democrats, objects to the bill, arguing it would likely lead to overfishing and would "interfere with the tremendous success achieved in rebuilding overfished fisheries by setting rebuilding targets that are not based on sound, credible science, and that unnecessarily extend the time to rebuild fisheries." Although almost half of fish stocks identified as overfished were rebuilt or showed good progress toward rebuilding over the past 10 years, a 2013 report by the National Research Council warns that some species remain at risk due to pressure to overfish.

In response to Democrats' concerns, Republicans argue the bill would still protect against overfishing while providing greater flexibility to local fisheries. In addition, the fishery law would be revised to reflect new science, management techniques, and local and regional fisheries' knowledge. Republican Don Young, who introduced the bill, says it was "written for fish and communities—not interest groups" and would ensure "the needs of our fisheries resources are balanced with the needs of our fishermen and coastal communities." The bill, which now heads to the Senate, would amend and reauthorize the Magnusons-Stevens Fishery Conservation and Management Act through 2019.

EFSA Publishes Scientific Opinion on the Safety of Caffeine
The European Food Safety Authority ("EFSA") Panel on Dietetic Products, Nutrition and

Allergies recently published a scientific opinion on the safety of caffeine. The opinion addresses possible adverse health effects of caffeine consumption from all dietary sources, including food supplements, in the general healthy population and in relevant specific subgroups of the general population (e.g., children, adolescents, adults, the elderly, pregnant and lactating women, subjects performing physical exercise). The opinion concludes that single doses of caffeine up to 200 mg do not give rise to safety concerns and addresses the impact of caffeine on specific subgroups of the population. The opinion also discusses whether other substances present in "energy drinks" may modify the possible adverse health effects of caffeine and/or the doses at which such adverse effects may occur.

Other News
WHO Declares Popular Herbicide Probably Causes Cancer in Humans

Food Industry Reps Testify in House on Proposed FDA Menu Labeling Requirements

WTO: India is Unfairly Blocking Imports of U.S. Poultry, Eggs

Democratic Senators Urge USDA to Finalize Poultry Pathogen Standards

Regulatory Updates

FDA Issues Final Rule Restricting Antibiotic Use in Animals
In the June 3, 2015, *Federal Register*, FDA published a final rule reducing the amount of antibiotics used in animal production. The rule amends the Veterinarian Food Directive ("VFD") drug regulations to improve clarity and food safety in products derived from treated animals. The VFD requires veterinarians to issue feed directives in the context of a valid veterinarian-client-patient relationship under the guidelines of the state where the veterinarian practices. ***The rule is effective October 1, 2015***.

FDA Announces Grants to Increase Food Safety Collaboration
In the May 28, 2015, *Federal Register*, FDA announced the availability of grant funds to support the National Center for Food Protection and Defense ("NCFPD"). The goal of NCFPD is to provide well-established and high-level access to food and agriculture sector organizations and coordination of electronic collaborative tools. The funds will allow for increased research into online tools for information sharing and the creation of a sustainable model of collaborative communication. Increased collaboration will result, among other things, in a greater ability to assess potential risks, greater food surveillance through inspections and testing, and improved rapid response capacity and efficiency. ***Applications are due July 15, 2015***.

FDA Announces Grants to Teach School-Aged Children About Food Safety and Nutrition
In the June 2, 2015, *Federal Register*, FDA announced the availability of grant funds for the support of the Center for Food Safety and Applied Nutrition's Education and Outreach Program Targeting School-Aged Children. The grantee must train 37 teachers to promote food safety and nutrition and use FDA's curriculum "Science and Our Food Supply" in classrooms for a one-year period. ***Applications are due July 1, 2015***.

FDA Amends Color Additive Regulations to Provide for Safe Use of Some Mica-Based Pearlescent Pigments
In the June 8, 2015, *Federal Register*, FDA amended the color additive regulations to provide for the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, nonalcoholic cocktail mixers and mixes, and egg decorating kits for coloring shell eggs. The amendments are in response to two color additive petitions submitted by industry. ***The rule is effective July 9, 2015***.

FDA Confirms Effective Date of Final Rule Amending Color Regulations to Expand Permitted Uses of Synthetic Iron Oxide
In the June 3, 2015, *Federal Register*, FDA confirmed that the final rule amending the

color additive regulations, issued in the March 20, 2015, *Federal Register*, became effective as of April 21, 2015. The final rule expanded the regulations to include the use of synthetic iron oxide as a color additive for use in hard and soft candy, mints, and chewing gum. ***The rule was effective April 21, 2015***.

USDA Announcements
• USDA's Animal and Plant Health Inspection Service ("APHIS") Issues Correction on the Hot Water Treatment of Oversized Mangoes
• APHIS Issues Preliminary Determination of Status for Non-Regulated Cotton
• APHIS Announces Availability of Preliminary Plant Risk Assessment and Draft Environmental Assessment of Genetically Engineered Maize
• APHIS Issues Double-Crested Cormorant Management Plan to Reduce Predation of Juvenile Salmonids in the Columbia River Estuary
• USDA Relaxes Minimum Quantity Exception for Potatoes Handled under Colorado Potato Marketing Order
• APHIS Proposes Rule for Importation of Phalaenopsis Spp. Plants for Planting in Approved Growing Media from China to the Continental U.S.
• USDA's Agricultural Marketing Service ("AMS") Issues Final Rule Establishing Free and Restricted Percentages for the 2014–15 Crop Year for Tart Cherries Grown in Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin
• AMS Proposes Amendments to Marketing Order Regulating Handling of Grapes Grown in Designated Area of Southeastern California

USDA Announced the Following Requests for Information
• Airplane Pilot Qualifications and Approval Record, Helicopter Pilot Qualifications and Approval Record, Airplane Data Record, and Helicopter Data Record
• Telecommunication Modernization Plan
• Disaster Supplemental Nutrition Assistance Program (D-SNAP)
• Evaluation of Demonstration Projects to End Childhood Hunger
• USDA National Clearinghouse Database Forms FNS 543 and FNS 543-A

USDA Announced the Following Information Collections Have Been Revised and/or Extended
• Reporting Requirements under Regulations Governing Inspection and Grading Services of Manufactured or Processed Dairy Products
• Customer/Stakeholder Satisfaction Surveys for the National Animal Health Monitoring System and the National Veterinary Services Laboratories
• National Institute of Food and Agriculture Proposal Review Process
• Floriculture Survey
• Business and Industry Guaranteed Loan Program
• Special Need Requests Under the Plant Protection Act
• Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery
• Health Certificates for the Export of Live Crustaceans, Finfish, Mollusks, and Related Products

USDA Announced the Following Information Collections Have Been Submitted to OMB
• Evaluation of Demonstration Projects to End Childhood Hunger

FDA Announced the Following Information Collections Have Been Submitted to OMB
• MedWatch: The Food and Drug Administration Medical Products Reporting Program

FDA Announced that the Following Collections Have Been Approved by OMB
• Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

FDA Issued the Following Draft and Final Guidance Documents
Draft Guidance for Industry: Veterinary Feed Directive Regulation Questions and Answers, June 3, 2015, *Federal Register*. ***Comments are due August 3, 2015***.

Draft Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD), June 1, 2015, *Federal Register*. ***Comments are due July 31, 2015***.

Draft Guidance for Industry: Voluntary Qualified Importer Program for Food Importers and Guidelines in Consideration of the Burden of the Voluntary Qualified Importer Program Fee Amounts on Small Business, June 5, 2015, *Federal Register*. ***Comments are due August 4, 2015.***

European Regulatory Updates

ECJ Issues Judgment on Labeling and Presentation of Foodstuffs
On June 4, 2015, the European Court of Justice ("ECJ") published a decision on the interpretation of Directive 2000/13/CEE on labeling, presentation, and advertising of foodstuffs (now replaced by Regulation no. 1169/2011). The case involved a food manufacturer who marketed a fruit tea with the wording "raspberry and vanilla adventure" together with depictions of raspberries and vanilla flowers on the packaging, when in fact the tea did not contain such ingredients. The ECJ held that EU labeling rules preclude such labeling from giving the impression, by means of the appearance, description, or pictorial presentation of a particular ingredient, that an ingredient is present when it is not, and this is apparent solely from the ingredient list on the foodstuff's packaging.

EFSA Publishes Scientific Opinion on Acrylamide in Food
On June 4, 2015, the Panel on Contaminants in the Food Chain ("CONTAM Panel") delivered a scientific opinion on acrylamide ("AA") in food. AA is a low molecular weight, highly water soluble, organic compound sometimes used in the production of polyacrylamides (polymers used in plastic food contact materials). The CONTAM Panel concluded that the current levels of dietary exposure to AA have no carcinogenic effects. However, although the epidemiological associations have not demonstrated AA to be a human carcinogen, the margins of exposure indicate a concern for carcinogenic effects based on animal evidence.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of National Advisory Committee on Microbiological Criteria for Foods, **June 10, 2015**, via audio conference call.

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

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

General Conference Committee of the National Poultry Improvement Plan, **July 23, 2015**, in Salt Lake City, UT.

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

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