Food, Dietary Supplement & Cosmetics Regulatory Update
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JONES DAY

Top News

President Trump to Nominate Scott Gottlieb as FDA Commissioner
According to a White House statement, President Trump intends to nominate Scott Gottlieb, M.D., as Food and Drug Administration ("FDA") Commissioner. Dr. Gottlieb has previously served in government in various capacities, including as deputy commissioner for medical and scientific affairs, and as a senior official at the Centers for Medicare and Medicaid Services during the Bush Administration. He is currently a venture partner at New Enterprise Associates, where he specializes in health care investments, and, according to his American Enterprise Institute ("AEI") biography, is a "resident fellow at the American Enterprise Institute where he studies the FDA and the Centers for Medicare & Medicaid Services (CMS). He also focuses on health care reform and political and clinical trends in medicine, including medical innovation and the development of new technology. He is concurrently a clinical assistant professor at New York University School of Medicine and advises the US Department of Health and Human Services as a member of the Federal Health IT Policy Committee." Dr. Gottlieb is also a director to American Pathology Partners, Medavante, Aptiv Solutions, and a member of GlaxoSmithKline's Product Investment Board. He was previously a director to Bravo Health and Molecular Insight Pharmaceuticals.

If confirmed by the Senate, Dr. Gottlieb would replace Robert Califf, who resigned in January 2017. Stephen Ostroff, M.D., has been acting Commissioner.

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New Cosmetic Bill Introduced this Year
In an attempt to amend the personal care products regulation, on January 13, 2017, Pete Sessions (R-TX) reintroduced a bill that amends the Federal Food, Drug, and Cosmetic Act to set forth provisions governing the regulation of cosmetics by FDA. The bill, titled the "Cosmetic Modernization Amendments of 2017" (H.R. 575), was previously introduced in 2015 (H.R. 4075) with no success. The bill proposes to redefine the term "cosmetic" so that "An article … that is intended only for topical external use to alter the appearance by temporarily affecting the structure or any function of the human skin, and that is not the subject of an approved new drug application under section 505, shall, for purposes of this Act, be treated only as a cosmetic and not a drug." The bill would require cosmetic manufacturer registration; submission of cosmetic and ingredient statements; reporting by cosmetic manufacturers, packers, and distributors of any serious and unexpected adverse events likely caused by a cosmetic; inclusion of contact information on cosmetic labels for serious adverse event reporting; codification of good manufacturing practice standards; creation of an FDA program to evaluate cosmetic and cosmetic ingredient safety; and establishment and maintenance of a National Cosmetic Regulatory Databank.

EFSA Proposes Simpler Food Safety Rules for Small Retailers
Following a request by the European Commission ("EC"), the European Food Safety Authority ("EFSA") has developed a simplified approach to food safety management in small food retail businesses, such as grocery shops, butchers, and bakeries. The approach includes guidelines to help small food retail businesses identify the most relevant biological, chemical, and physical hazards at each stage of the food production process, the activities or practices that make hazards more likely to occur, and the appropriate control measures. The simplified approach means, for example, that small food retailers are not required to have detailed knowledge of specific hazards. However, small food retailers need to be aware of the biological, chemical, and physical hazards or allergens that may be present in the production process, and need to know that a failure to undertake key control activities—such as correct chilled storage or separation of raw from cooked products—could increase consumer exposure to hazards. The traditional approach of food business operators—ranking and prioritizing hazards as required by current European Union ("EU") hygiene legislation before decisions on control measures can be taken—would not apply to small food retailers per EFSA's simplified approach.

EFSA Issues Draft Guidance on Substances in Food for Infants Below 16 Weeks
EFSA is launching a public consultation on its new draft guidance related to the risk assessment of substances present in food intended for infants below 16 weeks of age. EFSA's Scientific Committee proposes a new approach that can better support EU decision-making on the safe use of infant formula, and invites stakeholders and other interested parties to submit written comments by March 31, 2017. All correctly submitted comments will be assessed and, if found to be relevant, taken into consideration by the Scientific Committee in finalizing the guidance.

Eastern European Leaders to Address "Double Standards" for Food
On March 6, 2017, delegations from Hungary, the Czech Republic, and Slovakia presented their concerns to the EU Agriculture and Fisheries Council meeting regarding dual-quality foodstuffs in Europe. The concern is that products from the same producer that bear the same name and packaging may have a different level of quality, taste, and ingredients depending on the EU country in which these food products are being sold. In particular, Hungary, the Czech Republic, and Slovakia shared in a Note the results of a series of tests carried out on cases of "dual quality" in Europe and asked the EC to consider appropriate action including legislation at the EU level, if needed. The Outcome Report of the EU Agriculture and Fisheries Council states that the EC committed itself to work on the issue in the context of the consumer protection cooperation network and in the high-level forum for a better functioning of the food supply chain. Euractiv reports that the practice is legal in the EU as long as ingredients are declared. However, Central and Eastern European political leaders say it is unethical for products sold under the same brand to be inferior in quality in "new" EU Member States compared to "old"

Member States. The leaders of the Visegrád Group plan to adopt a joint declaration summing up the process of integration.

Other News

The Good Food Institute Petitions FDA Requesting Clarification on Naming Foods by Reference to "Traditional" Foods (e.g., "soy milk" by reference to "milk")

EPA Rejects Petition to Prohibit the Addition of Fluoridation Chemicals to U.S. Water Supply

India Urges the United States to Terminate Poultry Imports Dispute

Regulatory Updates

FDA Reopens Comment Period for Notice on Food Color Additive Regulations
In the March 1, 2017, *Federal Register*, FDA reopened the comment period for the draft guidance titled "Fruit Juice and Vegetable Juice as Color Additives in Food," which appeared in the *Federal Register* on December 14, 2016. Color additives must be approved for use by FDA and must be used only in compliance with the approved uses, specifications, and restrictions set out in FDA regulations. The authorization for the use of fruits and vegetables (21 CFR 73.250 and 21 CFR 73.260, respectively) as color additives in food are limited to the juice from certain fruits and vegetables and under certain conditions. The basis for these color additive regulations is that the fruit or vegetable from which the juice is made has been safely consumed as food. The fact that a plant material can be eaten does not necessarily mean that juice from such plant material meets the specifications of these regulations. Manufacturers have approached FDA about a variety of color additives made from plant materials, and FDA has provided responses on a case-by-case basis. For example, FDA has advised that juice made from purple corn and black carrots can meet the specifications of the vegetable juice color additive regulation, but juice made from safflower petals and hibiscus flowers do not meet the specifications. The draft guidance, when finalized, will assist manufacturers in determining whether a color additive derived from a plant material meets the specifications under certain FDA color additive regulations. ***Comments are now due May 1, 2017***.

APHIS Extends Comment Period on GMO Regulations and Plant Pest Regulations
In the February 10, 2017, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") extended the comment period for a proposed rule regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms ("GMOs") in order to update the regulations in response to advances in genetic engineering and understanding of the plant pest and noxious weed risk posed by GMOs, thereby reducing the burden for regulated entities whose organisms pose no plant pest or noxious weed risks. ***Comments are now due June 19, 2017***. In addition, in the February 13, 2017, *Federal Register*, APHIS extended the comment period for a proposed rule regarding the movement and environmental release of biological control organisms and to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting permit exceptions. The proposed rule would also revise regulations regarding soil movement. ***Comments are now due April 19, 2017***.

APHIS Delays Effective Date of Select Agent and Toxin Regulations
In the February 16, 2017, *Federal Register*, USDA's APHIS delayed the effective date of a final rule amending the select agent and toxin regulations, including new provisions to address the inactivation of select agents, biocontainment and biosafety, and clarifying regulatory language concerning security, training, incident response, and records. ***The effective date of the final rule is now March 21, 2017***.

AMS Extends Comment Period for Several Rules
In the February 17, 2017, *Federal Register* (*see* here, here, and here), USDA's Agricultural Marketing Service ("AMS") extended the comment period for three proposed rules: (i) a proposed rule that would remove 11 substances from the National List of Allowed and Prohibited Substances for use in organic production and handling; (ii) a proposed rule amending the Country of Origin Labeling ("COOL") regulations; and (iii) a proposed rule amending Perishable Agricultural Commodities Act ("PACA") regulations to clarify how growers and other principals may preserve their PACA trust rights and to provide guidance on the type of notification required to initiate USDA's investigations of alleged PACA violations. ***Comments are now due April 19, 2017, April 13, 2017, and March 15, 2017, respectively***. AMS also extended the comment period for an interim rule on amendments to the inspection requirements for fresh and processed fruits, vegetables, and other products to add an option for electronic inspection application submissions. ***Comments are now due March 23, 2017***. In addition, in the February 27, 2017, *Federal Register*, (*see* here and here), AMS extended the comment period for: (i) a proposed rule to, among other things, conduct a referendum to determine whether the issuance of a proposed Organic Research, Promotion, and Information Order is favored by certified organic producers, certified organic handlers, and importers of certified organic products; and (ii) a proposed rule on the establishment of an industry-funded research, promotion, and information program for certified organic products. ***Comments are now due April 19, 2017, for both proposed rules***.

FSIS Extends Comment Period for the Revision of the Nutrition Facts Labels for Meat and Poultry
In the February 22, 2017, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") extended the comment period for a proposed rule to amend the nutrition labeling requirements for meat (including fish of the order Siluriformes) and poultry products to better reflect the most recent scientific research and dietary recommendations, to improve the presentation of nutrition information to assist consumers in maintaining healthy dietary practices, and for consistency with recent regulatory changes finalized by FDA. ***Comments are now due April 19, 2017***.

FNS Extends Comment Period on Requirements for Processing of Donated Foods
In the February 27, 2017, *Federal Register*, USDA's Food and Nutrition Service ("FNS") extended the comment period on a proposed rule to revise and clarify the requirements for the processing of donated foods. The proposal is intended to: (i) incorporate successful processing options tested in demonstration projects; (ii) ensure accountability for donated foods presented for processing; and (iii) increase program efficiency. The rule would require multistate processors to enter into National Processing Agreements to process donated foods into end products, permit processors to substitute commercially purchased beef and pork of U.S. origin and of equal or better quality for donated beef and pork, and increase oversight of inventories of donated foods at processors. ***Comments are now due April 5, 2017***.

EU Regulatory Updates

European Parliament Resolves to Promote Natural Alternatives to Pesticides
On February 15, 2017, the Members of the European Parliament adopted a resolution calling on the EC to draw up proposals to fast-track the evaluation, authorization, and registration of low-risk pesticides. So far only seven active substances classified as "low risk" alternatives have been approved for use in the EU. According to Herbert Dorfmann (Italian member of the agriculture committee and one of the eight authors of the resolution that was adopted), "we are talking about organisms, viruses, bacteria, nematodes that have to go through a process of certification, which is not only very long, but also very expensive."

EC Invites Industry to Develop Self-Regulatory Rules for the Labeling of Alcoholic Beverages

On March 13, 2017, the EC adopted a report concerning the mandatory labeling of the list of ingredients and the nutrition declaration for all alcoholic beverages. Following the conclusions of the report, the EC has decided to invite the alcoholic beverages industry to develop, within a year, a self-regulatory proposal aiming to provide information on ingredients and nutrition of all alcoholic beverages. This proposal will be assessed by the EC. Should the EC consider the self-regulatory approach proposed by industry to be unsatisfactory, it would then launch an impact assessment to review further available options.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the National Organic Standards Board to assist the USDA in the development of standards for substances to be used in organic production and to advise the Secretary of Agriculture on any other aspects of the implementation of the Organic Foods Production Act, **April 13, 2017**, via webinar, and **April 19–21, 2017**, in Denver, CO.

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