JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
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Top News

FDA Answers Questions on Compliance Dates for Nutrition Initiatives
On October 7, 2016, FDA answered a series of questions concerning the compliance dates for various nutrition initiatives, such as the Nutrition Facts Label final rule and the vending machine labeling rule. FDA clarified that by July 26, 2018, manufacturers with $10 million or more in annual food sales will need to comply with the new requirements for the Nutrition Facts label, and vending machine operators with glass-front vending machines will have to comply with all requirements of the vending machine labeling rule. FDA also stated that by June 18, 2018, manufacturers must ensure their products no longer contain partially hydrogenated oils for uses that have not been otherwise authorized by FDA. In addition, FDA stated that the requirements for menu labeling affect restaurants and similar retail food establishments but not manufacturers. Lastly, FDA restated that the targets for sodium reduction the agency is developing are voluntary.

FDA Finalizes Two Guidance Documents Concerning Sunscreen TEAs
On October 11, 2016, pursuant to the deadline set out in the Sunscreen Innovation Act ("SIA"), FDA finalized two of the four guidance documents published in draft form on November 23, 2015.

These guidance documents relate to the time and extent application ("TEA") process to request a new over-the-counter ("OTC") drug monograph for sunscreens or to amend an existing monograph to recognize that a sunscreen active ingredient or condition is

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generally recognized as safe and effective ("GRASE"). The final versions of these two guidance documents, titled "Withdrawal of a 586A Request or Pending Request" and "Section 586C(c) Advisory Committee Process," are almost identical to the draft guidance documents. FDA received only two comments for each of them, all of which were rejected by the agency.

The first guidance addresses the expected effect of a withdrawal on key phases of the SIA process, including withdrawals made prior to or after the initial eligibility determination, the submission of safety and efficacy data, the filing determination, or the GRASE determination. This guidance also discusses the submission of a new 586A request for the same sunscreen ingredient for which a 586A or pending request had been previously submitted and withdrawn.

The second guidance provides background information on the OTC sunscreen monograph process, as well as on the Agency's intended process for convening the Nonprescription Drugs Advisory Committee ("NDAC"). It also recommends procedures for sponsors of 586A requests and for sponsors of pending requests to follow in requesting an NDAC meeting. This guidance also explains how FDA intends to process these requests and describes the factors the agency may consider in determining whether and when to refer such requests to the NDAC.

FDA Updates the Manufactured Food Regulatory Program Standards
This month, FDA revised food safety standards for state regulatory programs that oversee food facilities that manufacture, process, pack, or hold foods. These regulatory program standards, known as the Manufactured Food Regulatory Program Standards ("MFRPS"), were first issued by the agency in May 2007 and comprise 10 standards designed to help federal and state agencies better direct their regulatory activities toward reducing foodborne illness hazards. Elements of the standards include the program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. The 2016 updates include newly defined terms, new sections and appendices, and updates to each of the current standards.

The goal of the MFRPS is to enhance the nation's food safety, provide the tools and resources to enable state food regulatory programs to build strong infrastructures and systems that complement national uniformity and promote an integrated food safety system, promote quality regulatory programs through continuous self-improvement, and improve communication among regulatory and public health partners.

European Parliament Calls for a Ban of BPA in all Food Contact Materials
On October 6, 2016, 91 percent of the Members of the European Parliament adopted a report requesting the European Commission to consider banning the use of Bisphenol A ("BPA") from all food contact materials ("FCMs") after identifying it as a Substance of Very High Concern ("SVHC'"), which is prohibited in FCMs. BPA is a chemical that is mainly used in combination with other chemicals to manufacture plastics and resins. For example, BPA is used in polycarbonate, a high-performance transparent, rigid plastic. Polycarbonate is used to make food containers, such as returnable beverage bottles, infant feeding bottles, tableware, and storage containers. Residues of BPA are also present in epoxy resins used to make protective coatings and linings for food and beverage cans and vats. BPA can migrate in small amounts into food and beverages stored in materials containing the substance.

The European Commission, which issued a draft regulation to reduce the "tolerable daily intake" or "TDI" from 50 micrograms per kilogram of body weight per day (µg/kg of bw/day) to 4 µg/kg of bw/day, concluded in January 2015 that BPA poses no health risk to consumers of any age group at current exposure levels and is not bound by the European Commission's initiative. See our previous Jones Day *Update.* While the safety of BPA in FCMs is being evaluated, the European Food Safety Authority is conducting a study for

the potential effects of BPA on the immune system.

Other News
The World Health Organization Urges the Implementation of Fiscal Policies to Reduce Sugary Drinks Intake

FDA Creates SCORE, the Strategic Coordinated Oversight of Recall Execution Team

The United Nations Adopts Policy Recommendations for Animal Welfare in Farming

Regulatory Updates

FDA Requests Nominations for Food Advisory Committee
In the October 21, 2016, *Federal Register*, FDA requested nominations for voting members to serve on the Food Advisory Committee, Office of Regulations, Policy, and Social Sciences, Center for Food Safety and Applied Nutrition. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (i) broad scientific and technical food- or cosmetic-related issues; (ii) the safety of food ingredients and new foods; (iii) labeling of foods and cosmetics; (iv) nutrient needs and nutritional adequacy; and (v) safe exposure limits for food contaminants. Nominations received on or before December 20, 2016, will be given first consideration for membership. Nominations received after December 20, 2016, will be considered for nomination to the committee as later vacancies occur.

FDA Files Color Additive Petition
In the October 7, 2016, *Federal Register*, FDA announced it filed a petition, submitted by Wm. Wrigley Jr. Company, proposing that the color additive regulations be amended to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum. The color additive petition was filed on September 1, 2016.

FDA Extends Comment Period for Dietary Ingredient Notification and Related Issues Guidance
In the October 4, 2016, *Federal Register*, FDA extended the comment period for the revised draft guidance for industry titled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," which appeared in the Federal Register of August 12, 2016. The revised draft guidance aims at helping industry in evaluating whether to submit a premarket safety notification for a new dietary ingredient ("NDI"), or for a dietary supplement containing an NDI, and in preparing such premarket safety notifications, among other things. The comment period was scheduled to end on October 11, 2016, but ***comments are now due December 12, 2016***.

FSIS Updates Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission
In the October 5, 2016, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") announced the availability of an updated version of the Agency's compliance guideline on documentation needed to support animal-raising claims on product labels that must be submitted for agency approval before they can be used on product labels. The updated guideline reflects FSIS's current position and procedures for reviewing animal-raising claims and includes explanations of animal-raising claims that FSIS may approve and the types of supporting documentation that the Agency requires to be submitted to support these claims. ***Comments are due December 5, 2016***.

FSA Implements EZ Guarantee Program and Micro Lender Program Status
In the October 21, 2016, *Federal Register*, USDA's Farm Service Agency ("FSA") amended the guaranteed Farm Loan Programs ("FLP") regulations to implement an EZ Guarantee Program and establish an additional lender status. The EZ Guarantee Program intends to help lenders reduce costs of underwriting and servicing loans to help meet the unique financing needs of small farm operations. The intended effects of the rule are to

make guaranteed loan programs more widely available and attractive to small farm operations and the lenders who work with those farm operations through a more flexible underwriting analysis process, reduced application requirements, and faster FSA approval. In addition, FSA is amending the regulations to make a technical correction related to chattel appraisal appeals related to both guaranteed and direct loans. ***The rule was effective immediately, and comments are due December 20, 2016***.

CCC Issues Final Rule to Implement the Agricultural Conservation Easement Program
In the October 18, 2016, *Federal Register*, USDA's Commodity Credit Corporation ("CCC") finalized an interim rule of February 27, 2015, to implement the Agricultural Conservation Easement Program ("ACEP") that was authorized by the Agricultural Act of 2014. NRCS received 1,055 comments from 102 respondents to the interim rule. In the recent *Federal Register* notice, NRCS responds to comments, makes adjustments to the rule in response to some of the comments received, and issues a final rule for ACEP implementation. ***The rule was effective October 18, 2016***.

APHIS Solicits Nominations for the Animal Health Advisory Committee
In the October 12, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") solicited nominations for membership for the Secretary's Advisory Committee on Animal Health ("Committee") to serve for terms of two years. The Committee advises the Secretary of Agriculture on strategies, policies, and programs to prevent, control, or eradicate animal diseases, and considers agricultural initiatives of national scope and significance and advises on matters of public health, conservation of national resources, stability of livestock economies, livestock disease management, and traceability strategies, prioritizing animal health imperatives and other related aspects of agriculture. ***Nominations are due November 28, 2016***.

ARS Issues Final Rule on General Administrative Policy for Non-Assistance Cooperative Agreements
In the October 11, 2016, *Federal Register*, USDA's Agricultural Research Service ("ARS") issued a final rule amending ARS regulations and adopting the Office of Management and Budget ("OMB") guidance "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" as the uniform guidance within the ARS's Research, Education, and Economics ("REE") mission area on the use, award, and administration of non-assistance cooperative agreements awarded pursuant to the National Agricultural Research, Extension, and Teaching Policy Act of 1977. This rulemaking intends to reduce the administrative burden for non-federal entities receiving federal funds under non-assistance cooperative agreements while reducing the risk of waste, fraud, and abuse. Accordingly, proper use of these non-assistance cooperative agreements promotes and facilitates partnerships between the REE agency and the cooperator in support of research, extension, and education projects of mutual benefit to each party. ***The rule was effective October 11, 2016***.

EU Regulatory Updates

European Commission Approves a New Steviol Glycocide as a Sweetener
On October 13, 2016, the European Commission amended the Annex to Regulation (EU) 231/2012 laying down specifications for food additives, by adding a new steviol glycoside "Rebaudioside M" onto the list of permitted steviol glycosides with E 960. Steviol glycosides are sweeteners that are extracted from the leaves of stevia rebaudiana, which is a plant cultivated in South America.

Upcoming Meetings, Workshops, and Conferences

Public Meeting of FDA to discuss menu labeling, **November 16–17, 2016**, in Oakland, CA.

Public Meeting of the National Organic Standards Board to discuss implementation of the Organic Foods Production Act, **November 16–18, 2016**, in St. Louis, MO.

Public Meeting of AMS's Plant Variety Protection Board, **December 5–6, 2016**, in Chicago, IL.

Public Meeting of FDA's Sixth National Consumer Food Safety Education Conference, **January 25–27, 2017**, in Washington, D.C.

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