Food, Dietary Supplement & Cosmetics Regulatory Update
Vol. IV | Issue 4
JONES DAY

Food, Dietary Supplement & Cosmetics Regulatory Update

Top News

Senate Confirms Dr. Gottlieb's Nomination as FDA Commissioner

On May 9, 2017, the Senate confirmed Dr. Scott Gottlieb as the next FDA commissioner. With a 57-42 vote, the Senate filled the commissioner position most recently held by Dr. Robert Califf, who resigned in January 2017 and was replaced in the interim by Dr. Stephen Ostroff. Dr. Gottlieb, a physician, policy analyst, and entrepreneur assured in his confirmation hearing he will make it his mission "to fight for those families [whose lives and futures are affected by the decisions made by FDA] every single day, and ensure that FDA puts their interest first." Dr. Gottlieb also stressed he will lead the FDA as "an impartial and passionate advocate for public health" and offered to work for better efficiency and better safety while also remaining "faithful to FDA's gold standard for regulatory conduct."

Earlier, on April 27, 2017, the Senate Committee for Health, Education, Labor and Pensions ("HELP") voted 14-9 on Dr. Gottlieb's nomination. Accompanying the action by the HELP Committee, Sens. Sherrod Brown (D-OH), Maggie Hassan (D-NH), Edward J. Markey (D-MA), Elizabeth Warren (D-MA), and Sheldon Whitehouse (D-RI) sent a letter to Dr. Gottlieb requesting details about the nature of his work and financial relationship with the drug company Cephalon while at FDA previously. A recently published article had stressed that when he was Deputy Commissioner of the FDA Gottlieb "engaged with the DEA on behalf of…Cephalon to increase the amount of fentanyl available for it to manufacture its products."

Dr. Gottlieb has previously served in government in various capacities, including as deputy commissioner and as a senior official at the Centers for Medicare and Medicaid Services during the Bush Administration. Gottlieb, who stated he would divest his interests of any FDA-regulated companies, is a venture partner at New Enterprise Associates, a clinical assistant professor at New York University School of Medicine, and has provided consulting services to several drug companies. For more information on Dr. Gottlieb's nomination, please see our Food, Dietary Supplement and Cosmetic Update, Vol. IV, Issue 2.

[Go to Top]

CONTACTS

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Jonathan Berman
Washington

Françoise S. Labrousse
Paris

Ales Bartl
Brussels

Marina E. Moreno
Washington

Elinor Pecsteen
Brussels

RELATED PRACTICES

FDA Regulatory & Compliance Counseling

Health Care

Life Sciences

FDA Postpones Menu Labeling Rule Again

On May 1, 2017, FDA announced it was extending the compliance date for the menu labeling final rule from May 5, 2017, to May 7, 2018. The rule requires calorie information to be listed on menus and menu boards of restaurants and other retail food establishments that are part of a chain of 20 or more locations, do business under the same name, and offer for sale substantially the same menu items. Compliance with the 2014 final rule has been postponed several times. The final rule was originally set to go into effect in December 1, 2015, but implementation was initially delayed amid complaints the rule was too broad and inflexible.

Then, the omnibus appropriations bill for 2016 required FDA to postpone the December 2016 compliance date until one year after the agency finalized its draft Level 1 guidance on menu labeling. The guidance was finalized in May 2016, and the final rule was set for compliance on May 5, 2017.

In the interim final rule that FDA published on May 4, 2017, extending the compliance date, FDA requested comments, stating it was particularly interested in "hearing about approaches to reduce the regulatory burden or increase flexibility with respect to: (1) Calorie disclosure signage for self-service foods, including buffets and grab-and-go foods; (2) methods for providing calorie disclosure information other than on the menu itself, including how different kinds of retailers might use different methods; and (3) criteria for distinguishing between menus and other information presented to the consumer." ***Comments are due July 3, 2017.***

[Go to Top]

United States and Australia: Comparable Food Systems

On April 19, 2017, FDA announced that both the United States and Australia have recognized each other's food safety systems as comparable to each other. This is the third time that the FDA has given this recognition to a country, the first being New Zealand in 2012 and the second being Canada in 2016.

The FDA and the Australian Department of Agriculture and Water Resources have used the standards set forth in the International Comparability Assessment Tool ("ICAT") to evaluate whether a country's system of protections is similar to the other and whether their food safety authority or authorities provide similar oversight and monitoring activities for food produced under their jurisdiction. The ICAT indicates that foreign food safety system recognition should only be issued after evaluating the country's domestic and export food safety system, including: its regulatory foundation; training, inspection, program assessment and inspection audit, and compliance and enforcement program; food-related illness and outbreaks; industry and community relations; program resources; international communication and harmonization; and laboratory support.

Although imports from Australia must continue to comply with U.S. statutory and regulatory requirements to ensure safety and proper labeling, including the new standards adopted under the FDA Food Safety Modernization Act, systems recognition establishes a framework for regulatory cooperation in a variety of areas that range from scientific collaboration to outbreak response. For example, having comparable food safety systems means each partner intends to consider the oversight of the other when prioritizing inspection activities.

[Go to Top]

FDA Issues Further Guidance Related to FSVP

On May 11, 2017, FDA announced a new updated fact sheet and a guidance related to the use of a Unique Facility Identifier that is acceptable under the Foreign Supplier Verification Program ("FSVP") regulation. The three-page fact sheet responds to questions such as (i) who's covered by the rule (see also chart prepared by FDA), (ii) what to do if covered by the rule, (iii) when would modified requirements apply under the rule, (iv) what foods and beverages are exempt from the rule, and (v) what are the FSVP compliance dates.

The guidance states that beginning on May 30, 2017, the date when the FSVP final rule is set to take effect, the filer of food offered for entry into the United States will have to transmit through the U.S. Customs and Border Protection Automated Commercial Environment system a code to identify whether the product is subject to FSVP regulation or not. The entity role code to indicate the article of food and importer are subject to FSVP regulation is "FSV." In this case, the filer will also have to indicate the

importer's name, email address, and DUNS number as the UFI recognized as acceptable by FDA. For now, FDA is allowing filers to state "UNK" (to represent "unknown") if the importer has not yet provided a Dun & Bradstreet Data Universal Numbering System ("DUNS") number. If the food article is not subject to the regulation yet, the code must be "FSX," and if exempt from compliance because the food will be used for research or evaluation, the code must be "RNE." FDA stated that if codes are not transmitted the entry will be rejected and the filer will have to retransmit the entry line under the correct code.

[Go to Top]

The European Commission Amends Plastic Food Contact Materials Legislation

On April 28, 2017, the European Commission issued Regulation 2017/752, amending Regulation 10/2011 on plastic materials and articles intended to come into contact with food. The main changes include (i) new limits for some substances that are authorized in plastic food contact materials, (ii) a maximum migration level for nickel: 0.02 mg/kg of food, and (iii) an amendment to the rules for the use of food stimulants that are assigned for the testing of overall migration. The regulation is set to become applicable in May 2018.

[Go to Top]

European Food Safety Authority Launches Public Consultation on the Risk Assessment of GMO at Low Level

The European Food Safety Authority ("EFSA") has launched a public consultation on a draft guidance document on the risk assessment of genetically modified organisms ("GMOs") present at low levels in food and feed material. The draft guidance advises which criteria are necessary for a conclusion that a low level presence (maximum 0.9 percent) of genetically modified plant material in food and feed is safe. GMO material at this level is not subject to the mandatory GMO labeling requirement, as it is typically the unintentional result of unavoidable technical circumstances. However, it is the responsibility of each operator placing such products on the EU market to carry out a risk assessment to determine whether such levels are safe. ***Comments are due by June 13, 2017.***

[Go to Top]

Other News

Senate confirms former Georgia Republican Gov. Sonny Perdue as Secretary of Agriculture; Secretary Purdue creates undersecretary position for Trade and Foreign Agricultural Affairs, focused exclusively on international trade.

A conversation with Donald Prater: "Taking a Modern, Integrated Approach to Advancing the Safety of Imported Food"

A Conversation with Eric Brown and Marc Allard: "Sharing Whole Genome Sequencing with the World"

[Go to Top]

Regulatory Updates

FDA Amends Food Additive Regulations

In the May 4, 2017, Federal Register, FDA amended the food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because this use has been abandoned. This action, taken in response to a petition filed by Keller and Heckman LLP on behalf of the Society of the Plastics Industry, Inc., means that use of potassium perchlorate covered by the regulation is no longer authorized.

[Go to Top]

USDA Requests Comments on Actions to Take Regarding The

Packers and Stockyards Act

In the April 12, 2017, Federal Register, USDA announced its intention to pursue one of several actions on the Interim Final Rule ("IFR") of the Packers and Stockyards Act, published in the Federal Register on December 20, 2016, by USDA's Grain Inspection, Packers and Stockyards Administration. USDA asked the public to comment as to the possible actions USDA should take in regards to the disposition of the IFR. The IFR addresses the scope of sections 202(a) and (b) of the Packers and Stockyards Act, 1921 ("P&S Act"), as amended and supplemented in order to clarify that conduct or action may violate the P&S Act without adversely affecting, or having a likelihood of adversely affecting, competition. The IFR was originally set to take effect on February 21, 2017, and is now being extended to October 19, 2017. ***Comments are due June 12, 2017.***

[Go to Top]

USDA Requests Comments on Actions to Take Regarding the Organic Livestock and Poultry Practices Second Proposed Rule

In the May 10, 2017, Federal Register, USDA announced its intention to pursue one of several actions on the Organic Livestock and Poultry Practices Final Rule ("FR") published in the Federal Register on January 19, 2017, by USDA's Agricultural Marketing Service. USDA asked the public to comment on the possible actions USDA should take in regards to the disposition of the FR. The FR amends the organic livestock and poultry production requirements in the USDA organic regulations by adding new provisions for livestock handling and transport for slaughter and avian living conditions; and expands and clarifies existing requirements covering livestock care and production practices and mammalian living conditions. The FR was originally set to take effect on March 20, 2017, and is now being extended to November 14, 2017. ***Comments are due June 9, 2017.***

[Go to Top]

European Updates

Pesticide Residues Detected in Almost All European Foods

On April 25, 2017, EFSA issued reporting data for 2016 on pesticide residues in food and feed. Based on the report, of the 84,341 samples analyzed, 97.2 percent contained traces of one or more available 774 pesticides. One third of all the pesticides detected are illegal in the European Union. Among non-EU sources, 5.6 percent were found to contain pesticide residues above the EU limits (for authorized pesticides). Among EU-sourced products, 1.7 percent of samples were over the legal limits. The data in this report might be used by the national enforcement authorities to better target their inspections.

[Go to Top]

Italy Introduces New Labeling Law for Dairy Products

On April 20, 2017, an Italian Decree came into force requiring Italian dairy products operators to indicate the country where milking was carried out and where the product was then processed. The decree applies to milk, butter, yogurt, and mozzarella and other cheeses produced from milk of any type that are placed on the market in Italy. It, therefore, does not apply to products produced in Italy and then exported to another country.

[Go to Top]

Upcoming Meetings, Workshops, and Conferences

Public Meeting of the General Conference Committee of the National Poultry Improvement Plan, May 18, 2017, in Portland, ME.

Public Meeting of FDA, titled "International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR-11 Meeting," May 25, 2017, in College Park, MD.

[Go to Top]

Follow us on: 

Jones Day is a legal institution with more than 2,500 lawyers on five continents. We are One Firm Worldwide[SM].