Food, Dietary Supplement & Cosmetics Regulatory Update
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Top News

FDA Updates Guidance Related to Food Facility Registration
This month, in the middle of the renewal period for registration of food facilities, FDA has published the seventh edition of its draft guidance "Questions and Answers Regarding Food Facility Registration," which clarifies the Amendments to the Registration of Food Facilities final rule of July 14, 2016 (in effect since September 12, 2016). Details about the final rule can be found in a previous issue of Jones Day's *Food, Dietary Supplement & Cosmetics Regulatory Update*.

The draft guidance contains 15 sections with approximately 60 answers to questions, including what information must be submitted to register, update, cancel, or renew registration of a facility, and what the consequences of failing to do so are. Some of the topics that have been clarified by FDA are the meanings for each of the activity types under which a facility can be registered, and the fact that if a facility's initial registration is submitted prior to October 1 of a biennial renewal year (food facility registration is required every other even-numbered year), a renewal must still be submitted for the facility during the period beginning on October 1 and ending on December 31.

In addition, FDA stated that a company's DUNS number is FDA's preferred unique facility identifier ("UFI"), and the Agency will publish any additional UFIs it might recognize as acceptable before the requirement takes effect on October 1, 2020. FDA will consider comments for finalizing the guidance if submitted by February 6, 2017.

FDA Proposes Guidance on Hazard Identification in Documents Accompanying Food

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RELATED PRACTICES

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On October 31, 2016, FDA announced the availability of a draft guidance for industry titled "Describing a Hazard that Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry." This draft guidance explains FDA's current thinking on statements made by an entity in documents accompanying food, which disclose that certain hazards have not been controlled by that entity as required by certain provisions in the four final rules—Preventive Controls for Human Food, Preventive Controls for Food for Animals, Produce Safety Regulation, and Foreign Supplier Verification Programs for Importers of Food for Humans and Animals. FDA provides that a disclosure statement would be required mostly for biological hazards, for which general terms may be used (e.g., "microbial pathogens" rather than "*Salmonella*"). However, a manufacturing/processing facility that chooses not to control chemical or physical hazards, and relies on its customers to do so, would have to indentify such hazards using a specific term, such as "mycotoxins," "aflatoxin," or "stones." These disclosures must be made in "documents of the trade": documents accompanying the food such as "labels, labeling, bill of lading, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that a food safety manager for the customer is likely to read." FDA does not consider it sufficient to reference a website in a document of the trade without including the disclosure statement itself. Finally, FDA does not recommend documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions to be used as documents of the trade. ***Comments are due May 1, 2017***.

California's Sonoma County Bans GMO Crops

On November 8, 2016, voters in Sonoma County, California approved 86,050 to 67,758 the "Sonoma County Transgenic Contamination Prevention Ordinance" ("Measure M"), prohibiting the propagation, cultivation, raising, or growing of genetically modified organisms ("GMOs") in the county. The Center for Food Safety was a main backer of the initiative, arguing that the ban preserves food safety and protects local and organic growers and producers who choose not to plant GMO seed. Critics of the California initiative argue that the ban may prevent those farmers who are not growing genetically modified crops now from using new technologies or methods in the future.

The Center for Food Safety has supported similar bans in other jurisdictions, such as Oregon's Jackson County and several Hawaii counties, including Maui County, where the ban was struck down by a federal district court as preempted by state and federal law. The district court's decision is currently on appeal to Ninth Circuit.

EFSA Publishes Guidance on Novel and Traditional Foods

On November 10, 2016, the European Food Safety Authority ("EFSA") published two guidance documents on novel food and traditional food from third countries. "Novel food" refers to food that European citizens have not consumed to a significant degree prior to May 1997. It includes food from new sources (e.g., krill oil rich in omega-3 fatty acids) and food obtained through the application of new technologies (e.g., nanotechnology) or by using new substances (e.g., phytosterols or plant sterols). "Traditional food" is a subset of novel food. The term relates to food traditionally consumed in countries outside the EU. It includes foods made from plants, microorganisms, fungi, algae, and animals (e.g., chia seeds, baobab fruit, insects, and water chestnuts).

The mentioned guidance documents follow the adoption of the new European regulation on novel food (Regulation (EU) 2015/2283) from November 2015. The regulation, which replaces the previous one from 1997, comes into effect in January 2018 introducing a centralized assessment and authorization procedure. The new guidance documents explain in detail the kind of information applicants need to provide for risk assessment, and how it needs to be presented before EFSA can assess the safety of the novel or traditional food.

European Parliament Calls for Limit on Industrial Trans Fats in Food

On October 26, 2016, Members of European Parliament ("MEPs") resolved to place

mandatory limits on industrially produced trans-fatty acids ("TFAs"). They did so out of concern that TFAs may increase the risk of cardiovascular disease, infertility, Alzheimer's disease, diabetes, and obesity in consumers. TFAs tend to be used in cheaper food, which means people on lower incomes are most exposed to foodstuffs with a higher TFA content. This in turn increases the potential for widening health inequalities, according to MEPs. Accordingly, MEPs called for the European Commission to propose an EU legal limit on the industrial TFA content of all foods as soon as possible, preferably within two years.

Other News

USDA's National Institute of Food and Agriculture Offers $4.4 Million under Its Veterinarian Medicine Loan Repayment Program to Subsidize Training to Veterinarians in Return for Serving in Shortage Situations

USDA Approves J.R. Simplot Co.'s Ranger Russet and Atlantic GMO Potato Varieties

Free Trade Agreement Between Canada and Ukraine to be Ratified Soon

Regulatory Updates

FDA Issues Final Guidance "FDA's Voluntary Qualified Importer Program"

In the November 14, 2016, *Federal Register*, FDA announced the availability of a guidance for industry titled "FDA's Voluntary Qualified Importer Program." The guidance describes the Voluntary Qualified Importer Program ("VQIP"), which provides for expedited review and importation of food offered for importation by importers who voluntarily agree to participate in the program. The guidance describes the eligibility criteria for, and benefits of, participation in VQIP. The guidance also provides information on submitting an application for VQIP participation, obtaining a facility certification for the foreign supplier of a food imported under VQIP, the VQIP user fee, conditions that might result in the revocation of VQIP eligibility, and criteria for reinstatement of eligibility. FDA plans to begin accepting applications for VQIP on January 1, 2018, for participation in fiscal year 2019 beginning October 1, 2018.

FDA Issues Guidance "Questions and Answers Regarding Food Facility Registration"

As mentioned above, in the November 8, 2016, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Questions and Answers Regarding Food Facility Registration (Seventh Edition)." This draft guidance contains 15 sections providing updated information relating to the food facility registration requirements in the Federal Food, Drug, and Cosmetic Act. Sections are: (a) who must register?; (d) when must you register or renew your registration?; (e) how and where do you register or renew your registration?; (f) what information is required in the registration?; (g) what optional items are included in the registration?; (h) how and when do you update your facility's registration information?; (i) how and when do you cancel your facility's registration information?; (j) what other registration requirements apply?; (k) what are the consequences of failing to register, renew; update, or cancel your registration?; (l) what does assignment of a registration number mean?; (m) is food registration information available to the public?; (n) waiver request; (o) general registration questions; (p) suspension of registration; and (q) compliance dates. ***Comments are due February 6, 2017***.

FDA Proposes Guidance on Hazard Identification in Documents Accompanying Foods

As mentioned above, in the October 31, 2016, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Describing a Hazard that Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry." This draft guidance explains FDA's current thinking on disclosure statements, which must be made in "documents of the trade" accompanying food, that certain hazards have not been controlled by that

entity as required by certain provisions in the four final rules—Preventive Controls for Human Food, Preventive Controls for Food for Animals, Produce Safety Regulation, and Foreign Supplier Verification Programs for Importers of Food for Humans and Animals. This document describes FDA's current thinking and recommendations on how to describe the hazard under each of the four rules and which documents the Agency considers to be "documents of the trade" for the purpose of disclosure statements. ***Comments are due May 1, 2017***.

FDA Proposes Updating Appropriate RACC for Flavored Nut Butter Spreads
In the November 2, 2016, *Federal Register*, FDA announced the establishment of a docket to receive comments, particularly data and other information, on the appropriate reference amount customarily consumed ("RACC") and product category for flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored), and products that can be used to fill cupcakes and other desserts, such as cakes and pastries. FDA is taking this action in part because it has recently issued a final rule updating certain RACCs, and it has also received a citizen petition from Ferrero USA, Inc. asking FDA either to issue a guidance recognizing that "nut cocoa-based spreads" fall within the "honey, jams, jellies, fruit butter, molasses" category for purposes of RACC determination, or to amend the regulation to establish a new RACC category for "nut cocoa-based spreads" with a RACC of one tablespoon. FDA is also taking this action in response to a request to amend FDA's serving size regulations to establish a RACC and product category for cupcake filling. ***Comments are due January 3, 2017***.

FDA Issues Guidance Documents to Assist with Compliance of the Preventive Controls Rules
In the November 1, 2016, *Federal Register,* here and here, FDA announced the availability of two guidance documents for industry titled "What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" and "What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food"—Small Entity Compliance Guide. The small entity compliance guides are intended to help small entities comply with the final rules titled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals," and "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food," respectively. The guidance documents include definitions, compliance dates for their respective exceptions, and answers related to a variety of aspects concerning the current good manufacturing practices, as well as the hazard analysis and preventive controls facilities must have in place to be in compliance with the final rule.

FDA Proposes to Update Tolerances for Residues of New Animal Drugs in Food
In the October 28, 2016, *Federal Register*, FDA proposed to amend its 2012 document titled "New Animal Drugs; Updating Tolerances for Residues of New Animal Drugs in Food." The document proposed to revise the animal drug regulations regarding tolerances for residues of approved and conditionally approved new animal drugs in food by standardizing, simplifying, and clarifying the determination standards and codification style. FDA also proposed to add definitions for key terms. In this document, FDA is proposing to revise or remove some of the previously proposed definitions (e.g., removing the definition for "regulatory method"), taking into account comments the Agency received, and to more accurately reflect the rationale FDA relied on in the past to approve certain new animal drugs without a tolerance. FDA is reopening the comment period only with respect to the specific issues identified in this supplemental proposed rule. ***Comments are due December 27, 2016***.

FDA Files Food Additive Petition
In the November 8, 2016, *Federal Register*, FDA announced that Novus International, Inc. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement

dairy heifers. Additionally, the petition proposes that the food additive regulations be amended to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food. ***Comments are due December 8, 2016***.

FSIS Announces Civil and Criminal Actions Against Individuals Who Inhumanely Handle Livestock
In the October 26, 2016, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") announced its intent to hold livestock owners, transporters, haulers, and other persons not employed by an official establishment responsible if they commit acts involving inhumane handling of livestock, in connection with slaughter when on the premises of an official establishment. The Agency intends to initiate civil or criminal action against these individuals. FSIS believes these actions will further improve the welfare of livestock handled in connection with slaughter by ensuring that all persons who inhumanely handle livestock in connection with slaughter are held accountable. ***Comments are due November 25, 2016***.

APHIS Proposes Rule Allowing Importation of Hass Avocados from Colombia
In the October 26, 2016, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") amended the fruits and vegetables regulations to allow the importation of Hass avocados from Colombia into the United States. As a condition of entry, Hass avocados from Colombia would have to be produced in accordance with a systems approach that would include requirements for importation in commercial consignments; registration and monitoring of places of production and packinghouses; pest-free places of production; grove sanitation, monitoring, and pest control practices; lot identification; and inspection for quarantine pests by the Colombian national plant protection organization. Additionally, avocados from Colombia would be required to be accompanied by a phytosanitary certificate with an additional declaration stating that the avocados have been produced in accordance with the proposed requirements.

APHIS Proposes to Allow Import of Orchids from Taiwan
In the October 26, 2016, *Federal Register*, USDA's APHIS proposed to amend the regulations governing the importation of plants to add orchid plants of the genus *Dendrobium* from Taiwan to the list of plants that may be imported into the United States in an approved growing medium, subject to specified growing, inspection, and certification requirements. The Agency is taking this action in response to a request from the Taiwanese government and after determining that the plants could be imported, under certain conditions, without resulting in the introduction into, or the dissemination within, the United States of a plant pest or noxious weed. ***Comments are due December 27, 2016***.

AMS Increases Assessment Rate for Apricots Grown in Designated Counties in Washington
In the October 27, 2016, *Federal Register*, USDA's Agricultural Marketing Service ("AMS") implemented a recommendation from the Washington Apricot Marketing Committee to increase the assessment rate established for the 2016–17 and subsequent fiscal periods from $0.75 to $1.40 per ton of Washington apricots handled under the marketing order. The fiscal period begins April 1 and ends March 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated. ***The rule is effective October 28, 2016***.

AMS Proposes to Amend the Quality Systems Verification Programs
In the November 07, 2016, *Federal Register*, USDA's AMS proposes to amend its regulations to better reflect the current needs of Quality Systems Verification Program ("QSVP") activities and to implement changes created by the merger of the AMS Livestock and Seed Program and the AMS Poultry Programs. These proposed changes include: amending the Livestock, Meat, and Other Agricultural Commodities QSVP to expand the commodities under the QSVP to include those authorized under the Agricultural Marketing Act of 1946; removing reference to "Livestock, Meat, and Other Commodities" in the title; more clearly identifying and defining the types of programs

and services offered under the QSVP; and making other technical and administrative changes. Simultaneously, AMS proposes to make conforming changes to the regulations pertaining to the Voluntary Grading of Shell Eggs and Voluntary Grading of Poultry Products and Rabbit Products to remove references to audit activities. ***Comments are due January 6, 2017***.

EU Regulatory Updates

EFSA Launches Public Consultation into "Cocktail Effects" of Chemicals
EFSA has drafted the terms of reference for a working group of the Scientific Committee on "Harmonization of Risk Assessment Methodologies for Human Health and Ecological Risk Assessment of Combined Exposure to Multiple Chemicals" ("Working Group"). The Working Group will develop a draft guidance document for human and ecological risk assessment of combined exposure to multiple chemicals using existing frameworks as starting points, and tiered approaches for each step (problem formulation, hazard identification, hazard characterization, exposure assessment, and risk characterization). Following input from this public consultation, the Working Group of the scientific committee will review the contributions and consider them in developing the guidance document. Interested parties are invited to submit written comments by November 30, 2016.

Upcoming Meetings, Workshops, and Conferences

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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