Food, Dietary Supplement & Cosmetics Regulatory Update
Vol. IV | Issue 7
JONES DAY

Food, Dietary Supplement & Cosmetics Regulatory Update

Top News

USDA Inspector General Recommends Reform of AMS Organic Program for Imports

The USDA Inspector General ("IG") reviewed the Agricultural Marketing Service's ("AMS") process used in determining whether exporting countries' organic standards are equivalent to USDA's organic standards, and whether imported organic products are in compliance with USDA's organic standards. AMS, through the National Organic Program ("NOP")—which develops rules and regulation for the production, handling, labeling, and enforcement of all USDA organic products, with the goal of ensuring that the products with the USDA organic seal meet consistent, uniform standards—is responsible for administering organic trade arrangements and agreements. Currently, NOP administers equivalency agreements with Canada, the European Union, Japan, Korea, and Switzerland, and has determined through recognition agreements that the countries of India, Israel, and New Zealand do not have organic standards in place or are not equivalent to NOP standards.

Based on the audit, the IG concluded:

- AMS's process for determining equivalency of organic standards lacks transparency, as NOP officials do not have a methodology in place to disclose the results of that process to the stakeholders;
- AMS is unable to provide reasonable assurance that NOP-required documents have been reviewed at U.S. ports of entry, as would be necessary to verify that imported agricultural products labeled as organic were from certified organic-offering farms and businesses that produce and sell organic products;
- AMS has not established and implemented controls at U.S. ports of entry to identify, track, and ensure that fumigated products are not sold, labeled, or represented as organic; and
- Onsite audits of foreign countries with which AMS has entered into equivalency or recognition agreements have not been conducted in a timely manner.

The IG provided nine recommendations to AMS to overcome these NOP deficiencies, and AMS responded with corrective actions committing to address the recommendations by July 2018.

In addition to the above, on October 25, 2017, USDA's AMS NOP released an interim instruction for all USDA-accredited certifiers and accredited certifiers authorized to operate under USDA organic recognition and equivalency arrangements. It explains the current certification requirements applicable to such certifiers and documentation needed to import organic products into the United States, certifiers' responsibilities in reviewing or issuing import-related documents, and handling instructions needed to maintain the organic integrity of imported organic products. The instructions also recommend best practices and provide examples that certifiers may use in order to comply with the existing regulations. NOP will accept comments until December 26, 2017.

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FDA Proposes New Compliance Dates for the Nutrition Facts Label and Service Size Final Rules

On October 2, 2017, FDA proposed to extend the compliance dates of the "Nutrition Facts Label" and "Service Size" final rules by approximately 18 months. Both final rules require updated nutrition information on the label of food, including dietary supplements; defined a single-serving container; required dual-column labeling for certain containers; updated, modified, and established certain reference amounts customarily consumed; and amended the label serving size for breath mints. The final rules originally appeared in the *Federal Register* of May 27, 2016, here and here. For further information on the final rules, see our previous Jones Date *Update*.

This proposed rule would extend the compliance date from July 26, 2018, to January 1, 2020, for manufacturers with $10 million or more in annual food sales, and from July 26, 2019, to January 1, 2021 for manufacturers with less than $10 million in annual food sales. FDA stated it took this action because, after careful consideration, it tentatively determined that additional time would help ensure that all manufacturers covered by the final rules have guidance from FDA to address certain technical questions and are able to complete and print updated Nutrition Facts labels for their products before they are expected to be in compliance with the final rules. The comment period closed on November 1, 2017.
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FDA Publishes Draft Guidance on Menu Labeling

On November 7, 2017, FDA issued a supplemental draft guidance to address concerns raised by stakeholders regarding the implementation of nutrition labeling required for foods sold in restaurants or similar retail food establishments that are part of a chain with 20 or more locations doing business under the same name and selling substantially the same restaurant-type food items. The menu labeling final rule, which has been labeled as too broad and inflexible, enters into effect on May 7, 2018. See our previous Jones Day *Update* for more information.

This question-and-answer guidance covers several topic areas: (i) calorie disclosure signage for self-service food, including buffets and grab-and-go food; (ii) various methods for providing calorie disclosure information, including those for pizza; (iii) criteria for distinguishing between menus and marketing material; (iv) compliance and enforcement; (v) reasonable basis, including the criteria for considering the natural variation of foods; (vi) criteria for covered establishments; and (vii) standard menu items. For clarity, the guidance includes several examples.

FDA has also decided to withdraw Questions and Answers 5.17 and 5.18 from its previous guidance titled "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods – Part II (Menu Labeling Requirements in Accordance With FDA's Food Labeling Regulations)," effective November 7, 2017. FDA will accept comments on this draft guidance from November 9, 2017, to January 8, 2018, after which FDA has stated it will move to finalize it. The Agency has also stated it is "fully committed" to keeping the May 7, 2018, compliance deadline.
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FDA Allows "Co-Manufacturers" Additional Time to Implement Certain Supply-Chain Program Requirements

On November 6, 2017, FDA announced the availability of a guidance for industry titled "Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food." The guidance announces that FDA does not intend to take enforcement action against a receiving facility that is a co-manufacturer and that is not in compliance with certain supply-chain program requirements of the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" regulations (preventive controls regulations) for food manufactured for the brand owner, under certain circumstances, until November 6, 2019.

The guidance addresses, for instance, situations where the brand owner audits the supplier or evaluates the supplier's performance as part of the process to approve such supplier, and the co-manufacturer describes these actions in its food safety plan and conducts any necessary supplier approval activities not conducted by the brand owner, such as maintaining a hazard analysis of the food or testing the raw material upon entry to its facility. FDA confirmed that in such situations it will not take enforcement action. Under the new final rules, the co-manufacturer is allowed to base its verification of suppliers on review of adequate documentation of the brand owner's supplier verification activities.

Industry has expressed concerns that current contracts between the brand owners and their suppliers may not in some instances allow the brand owner to share certain information about its suppliers to the co-manufacturer. FDA has stated that to provide time for contracts to be reviewed, FDA does not intend to enforce certain requirements of the final rules as described in the Guidance. In addition, it does not intend to take enforcement action under the Foreign Supplier Verification Programs regulation against an importer whose supply-chain program is subject to enforcement discretion under the preventive controls regulations until November 6, 2019.

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FDA Releases Training Module for Carriers Subject to the Sanitary Transportation Rule

On September 20, 2017, FDA released a one-hour training module, free of charge, to help carriers meet the requirements of FDA's Sanitary Transportation of Human and Animal Food Rule ("Sanitary Transportation Rule"). The Sanitary Transportation Rule requires rail and motor vehicle carriers covered by the rule to provide food safety training to their personnel engaged in transportation operations when the carrier is responsible, in whole or in part, for the sanitary conditions during transportation. The course is designed to provide basic food safety training to transportation operations personnel, providing personnel training on potential food safety problems, basic sanitary practices, and carrier responsibilities. The course is intended to complement industry best practices.

The course can be accessed by anyone by entering into FDA's website. The individual who completes it will be able to generate a certificate of completion from the website. FDA has stated that carriers subject to the training requirements must establish and maintain records documenting the training of operations personnel, which they may be asked to provide to FDA upon request. The first compliance date for businesses covered by the Sanitary Transportation Rule was April 6, 2017. The compliance date for small businesses covered by the rule is April 6, 2018.

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European Parliament Calls for Complete Glyphosate Ban by 2022

On October 24, 2017, the European Parliament adopted a nonbinding resolution opposing the European Commission's proposal to renew the authorization of this herbicide (marketed as Roundup by Monsanto) for an additional 10 years. Instead, according to the resolution, the EU should draw up plans to phase out the substance by 2022. Although the European Food Safety Authority ("EFSA") in their glyphosate assessment of 2015 concluded that the carcinogenic effect had not been established, glyphosate is considered a suspected carcinogen by the UN cancer agency, IARC. The way EFSA carried out the assessment of glyphosate (mainly pertaining to data selection) has been subject to criticism by several EU Member States.

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EU Issues New Labeling Regulation on Foods Marketed for Weight Control

On October 7, 2017, the European Commission ("EC") issued Regulation 2017/1798 related to the specific compositional and information requirements for foods marketed as a "total diet replacement for weight control." It sets out statements and additional nutrition declarations that should accompany such foods. In addition, its Annexes provide compositional requirements that such foods must meet in order to be marketed in the EU.

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France Introduces "Nutri-Score Labeling" System for Foods

On November 2, 2017, France issued a Decree introducing the voluntary labeling system for food products to reduce obesity. Following the United Kingdom's "traffic light" system, France has opted for its own food score system. The "Nutri-score," as it is called, gives a rating to any food (except single-ingredient foods and water) going from a dark green A (best) to a red E (worst), by weighing the prevalence of good and bad nutrients.

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Other News

FDA Proposes to Revoke Health Claim that Soy Protein Reduces Risk of Heart Disease (*see* Regulatory Update section for more information)

The California Environmental Protection Agency's OEHHA Accepts Request on Safe Use Determination for Chlorothalonil in Certain Foods Resulting from Pesticidal Use of the Chemical and Gives Opportunity for Public Comment

FDA Pesticide Analysis for FY 2015 Demonstrates Low Residue Levels

FDA Warns Companies that Dietary Supplements Containing Cannabidiol and Claiming to Treat or Cure Cancer Are Unapproved Drugs

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Regulatory Updates

FDA Announces Withdrawal of Food Additive Petitions

In the November 1, 2017, Federal Register, FDA announced the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2280 and 2276) proposing that the food additive regulations be amended to provide for the safe use of 25-hydroxyvitamin D3 in feed for swine, and for the safe use of ethoxyquin in vitamin D formulations, including 25-hydroxyvitamin D3, used in animal food. ***The food***

additive petitions were withdrawn on September 13, 2017.
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FDA Proposes Revoking the Authorization to Use Health Claims Related to Soy Protein and Coronary Heart Disease

In the October 31, 2017, *Federal Register*, FDA proposed to revoke its regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease on the label or in the labeling of foods. FDA is taking this action based on its review of the totality of publicly available scientific evidence currently available and its tentative conclusion that such evidence does not support its previous determination that there is significant scientific agreement among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease. The claim that soy proteins reduce the risk of coronary heart disease is one of the 12 that FDA has authorized to date, and this would be the first time FDA proposes to revoke a health claim. FDA has also stated that should FDA finalize this rule, the agency intends to allow the use of a qualified health claim, which requires a lower scientific standard of evidence than an authorized health claim, as long as there is sufficient evidence to support a link between eating soy protein and a reduced risk of heart disease. ***Comments are due January 16, 2018***.
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FDA Issues Two Guidance Documents on CGMP Requirements and "Solely Engaged" Exemptions for Animal Food

In the October 20, 2017, *Federal Register*, FDA announced the availability of two guidance documents for industry #235 titled "Current Good Manufacturing Practice Requirements for Food for Animals." This guidance is intended to help domestic and foreign facilities that are required to register as food facilities under the Federal Food, Drug, and Cosmetic Act determine whether and how they need to comply with the current good manufacturing practice requirements ("CGMP") of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule ("Preventive Controls Rule"). Changes from the previous draft guidance include additional explanation and examples, and the inclusion of a part 507 CGMP Assessment Tool in Appendix B to assist facilities in reviewing the implementation of CGMP requirements at their facility. Information regarding human food by-products for use as food for animals was removed and contained in draft GFI #239, titled "Human Food By-Products for Use as Animal Food" (August 25, 2016).

The second guidance document, titled "Application of the "Solely Engaged" Exemptions in Parts 117 and 507," discusses the applicability of the "solely engaged" exemptions for the Preventive Controls Rule. It explains when facilities are exempt from CGMP or preventive controls requirements because they are "solely engaged" in certain activities, such as the related to the holding or transportation of raw agricultural commodities, the storage of raw agricultural commodities (other than fruits and vegetables), the storage of unexposed packaged food, and other activities tied to the preparation of nuts and the ginning of cotton. The draft guidance also explains that the "solely engaged" exemptions do not apply when a facility is also conducting certain other activities. ***Comments for the second guidance are due April 18, 2018***.
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FDA Announces Food Additive Petition

In the September 14, 21, 22, 25, 2017, *Federal Register* (here, here, here, and here), FDA announced receipt of several petitions to amend the food additive regulations to provide for the safe use of gamma-linolenic acid safflower oil as a source of omega-6 fatty acids in dry food for adult cats in the maintenance life stage; the safe use of glyceryl polyethylene glycol (15) ricinoleate as an emulsifier in animal food that does not include food for cats, dogs, vitamin premixes, or aquaculture; the safe use of glyceryl polyethylene glycol (200) ricinoleate as an emulsifier in animal food that does not include food for cats, dogs, vitamin premixes, or aquaculture; the safe use of chromium DL-methionine as a nutritional source of chromium in cattle feed; and the safe use of silicon dioxide as a carrier for flavors for use in animal feed. ***Comments on the second and third food additive petitions were due October 23, 2017***.
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FDA Confirms Effective Date for Final Rule Listing Spirulina Extract as a Color Additive Exempt from Certification

In the September 20, 2017, *Federal Register*, FDA confirmed the effective date of August 3, 2017, for the final rule that appeared in the *Federal Register* of July 3, 2017, and that amended the color additive regulations to provide for the expanded safe use of spirulina extract to seasonally color hard-boiled shell eggs at levels consistent with good manufacturing practice.
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APHIS Adds Rust-Resistant Species and Varieties to Regulation

In the November 2, 2017, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") published a direct final rule notifying of its intention to amend the black stem rust quarantine and regulations by adding 15 varieties to the list of rust-resistant Berberis species and varieties and two varieties to the list of rust-resistant Mahonia species and varieties. ***The rule was effective November***

6, 2017.
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AMS Establishes De Minimis Quantity Exemption Threshold for the Softwood Lumber Program

In the October 26, 2017, *Federal Register*, USDA's AMS established a de minimis quantity exemption threshold exempting smaller manufacturers from assessments relating to a national research and promotion program for softwood lumber. In response to a 2016 federal district court decision, USDA conducted a new analysis to determine a reasonable and appropriate de minimis threshold. Based on that analysis, this rule establishes the de minimis quantity threshold at 15 million board feet (mmbf) and entities manufacturing (and domestically shipping) or importing less than 15 mmbf per year will be exempt from paying assessments under the regulations. ***The rule is effective November 27, 2017***.
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AMS Implements Minimum Quality and Handling Standards for Peanuts

In the October 20, 2017, *Federal Register*, USDA's AMS implemented a recommendation from the Peanut Standards Board to revise the minimum quality and handling standards for domestic and imported peanuts marketed in the United States. This action aims at relaxing the allowance for damaged kernels in farmers stock peanuts when determining segregation, and at increasing the allowance for damaged kernels under Segregation 1 from not more than 2.49 percent to not more than 3.49 percent. The requirements for Segregation 2 are also adjusted to reflect this change. The Peanut Standards Board recommended this change to align the incoming standards with recent changes to the outgoing quality standards and to help increase returns to producers. ***The rule is effective February 1, 2018***.
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GIPSA Updates the Public on its Determination on the Unfair Practices and Undue Preferences in Violation of the Packers and Stockyards Act

In the October 18, 2017, *Federal Register*, USDA's Grain Inspection, Packers and Stockyards Administration ("GIPSA"), Packers and Stockyards Program ("P&SP") notified the public that after review and careful consideration of the public comments received, GIPSA would take no further action on the proposed rule published on December 20, 2016. GIPSA invited comments on the proposed rule to amend the regulations issued under the Packers and Stockyards Act ("P&S Act"), and intended that the proposed rule would clarify the conduct or action that GIPSA considers unfair, unjustly discriminatory, or deceptive in violation of 7 U.S.C. 192(a).
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GIPSA Withdraws Interim Rule Addressing the Scope of Sections 202(a) and (b) of the P&S Act

In the October 18, 2017, *Federal Register*, USDA's GIPSA Packers and Stockyards Program withdrew the interim final rule ("IFR") published on December 20, 2016. Had the IFR become effective, it would have added a paragraph to the regulations issued under the P&S Act addressing the scope of sections 202(a) and (b) of the P&S Act, further explaining that certain conduct or actions, depending on their nature and the circumstances, could be found to violate the P&S Act without a finding of harm or likely harm to competition. GIPSA accepted and analyzed comments on the IFR received on or before March 24, 2017. In addition, in the April 12, 2017, *Federal Register*, GIPSA solicited and analyzed comments received on or before June 12, 2017, on four alternative actions regarding the disposition of the IFR. After careful review and consideration of all comments received, GIPSA decided to withdraw the IFR.
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AMS Withdraws Proposed Rule to the Export Apple Act and the Export Grape and Plum Act

In the October 15, 2017, *Federal Register*, USDA's AMS withdrew a proposed rule to change the reporting of export certificate information under regulations issued pursuant to the Export Apple Act and the Export Grape and Plum Act. After reviewing and considering the comments received, the agency decided not to proceed with this action. The proposed rule was withdrawn as of October 15, 2017.
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AMS Invites Comments on the Watermelon Research and Promotion Plan

In the September 27, 2017, *Federal Register*, USDA's AMS invited comments on realigning the production districts under the Watermelon Research and Promotion Plan for producer and handler membership on the National Watermelon Promotion Board, and adding four importer seats to the Board. These changes were recommended by the Board after a review of the production volume in each district as well as assessments paid by importers. The Plan requires that such a review be conducted every five years. This action would increase the number of importer seats from eight to 12, thereby increasing the number of Board members from 37 to a total of 41: 14 producers, 14 handlers, 12 importers, and one public member. ***Comments were due October 27, 2017***.
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EU Regulatory Updates

European Parliament Rejects Proposed Criteria for Endocrine Disruptors Identification

On October 4, 2017, the European Parliament ("EP") vetoed the EC's proposal for using certain criteria to identify endocrine disrupting chemicals ("EDCs") in biocides and pesticides, asking it to come up with a new proposal "without delay." In particular, the Parliament objected to the EC's proposal to exempt some substances, designed to attack an organism's endocrine system, from the used criteria. The EC will now have to draft a new version of the text, taking into account Parliament's input.
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EFSA Adopts Guidance Documents on Feed Additive Applications

On October 17, 2017, the European Food Safety Authority ("EFSA") adopted a series of Guidance documents related to the authorization of feed additives: (i) Guidance on the assessment of the safety of feed additives for the target species, (ii) Guidance on the assessment of the safety of feed additives for the consumer, and (iii) Guidance on the identity, characterization and conditions of use of feed additives.
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