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US Regulation of Food Products: What to Expect in 2019

Advisory

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The US Food and Drug Administration (FDA or the Agency) and the US Department of Agriculture's (USDA's) 2018 policy and regulatory activities have set the foundation for a robust 2019 policy agenda—once the partial shutdown of the US government ends. While we await the resolution of the shutdown—which has suspended all but the most urgent food regulatory tasks—and issuance of FDA's strategic plan for 2019, there are key FDA, USDA and legislative developments that occurred towards the end of 2018 that should be on the radar of every company that manufactures, sells or markets conventional food or dietary supplement products in the United States.

In particular, clients should be contemplating the impact of the (1) passage of the Agriculture Improvement Act of 2018 (the Farm Bill); (2) FDA statements regarding its mandatory food recall authority; (3) FDA updates to food standards of identity; (4) finalization of the USDA's bioengineered food disclosure standard; and (5) joint FDA and USDA regulation of cell-cultured meat products.

Below, we provide brief summaries of these developments that will likely be meaningful for 2019 and lead to further developments as the year moves on. If you have questions about any of these developments, please do not hesitate to contact us.

I. The Farm Bill and FDA's Position on Hemp-Derived Products in Food

On December 20, 2018, the Agriculture Improvement Act of 2018 (the Farm Bill) was signed into law.[1] In pertinent part, the Farm Bill removed hemp (*Cannabis sativa L.*),[2]from the definition of marijuana in the Controlled Substances Act (CSA) and removed tetrahydrocannabinols (THC) in hemp from Schedule I of the CSA.[3] As a result, cannabinoids derived from hemp, including cannabidiol (CBD), are no longer considered illegal substances under federal law. Given the vast commercial interest in developing and marketing CBD-containing products, this development is significant.

FDA reacted quickly to this shift in the law and proactively issued a statement on the same day, clarifying its position on cannabis and cannabis-derived products, including CBD.[4] Under the Farm Bill, FDA's authority to regulate products containing cannabis or cannabis-derived products is "explicitly preserved" and FDA will continue to "treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products . . ."[5] Dr. Gottlieb also expressed that FDA will take further steps to "better define" the Agency's "public health obligations in this area."[6] FDA has previously issued warning letters to companies illegally selling CBD products about which drug claims were made, marketing CBD products as dietary supplements or adding CBD to foods.

Dr. Gottlieb's remarks also specifically addressed foods and hemp. FDA's current position is that marketing food or dietary supplements containing CBD in interstate commerce is a violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), regardless of whether the CBD is hemp-derived.[7]This is not to say that FDA is precluding all pathways to legally marketing such products; as Dr. Gottlieb explained, FDA has the power to issue a regulation permitting the use of a pharmaceutical ingredient in a food or dietary supplement, and is considering whether to do so. However, this does not preclude the use of other hemp-derived substances in food. For example, on December 20, 2018, FDA stated that it has completed evaluation of three Generally Recognized as Safe (GRAS) notices for hulled hemp seeds, hemp seed protein, and hemp seed oil.[8] The products identified in the GRAS notices may now be lawfully marketed for the intended uses covered in the notices.

Companies interested in developing products derived from hemp or containing hemp compounds should stay tuned for the announcement of an FDA public meeting at which stakeholders will be invited to share information and challenges related to hemp products.[9] FDA intends to use the meeting to obtain feedback that will help inform the Agency's regulatory strategy for existing products and improving the efficiency and predictability of the pathways for marketing products containing cannabis or cannabis-derived compounds. In the meantime, Dr. Gottlieb's pronouncements should serve as both a reminder and a warning that should be heeded—FDA is in the business of regulating cannabis and cannabis-derived products, and may exercise its enforcement powers against companies illegally selling what the agency believes are violative products.

II. Increased Use of Mandatory Food Recall Authority by FDA

As part of the FDA Food Safety Modernization Act (FSMA) enacted in 2011, Congress gave FDA the authority to conduct mandatory food recalls.[10] Previously, FDA could only request that companies voluntarily recall violative products. FDA may now order a mandatory recall when FDA determines that there is a "reasonable probability that the article of food" is adulterated or misbranded and that the "use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA)."[11] FDA typically endeavors to cooperatively resolve recall issues with companies, rather than resorting to its mandatory recall authority, and has only called on its mandatory authority once—in April 2018, the Agency issued a mandatory recall order for all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals LLC due to Salmonella contamination.[12]

Increasing use of this mandatory recall authority should be anticipated, as reflected in Dr. Gottlieb's remarks accompanying the issuance of the final Mandatory Food Recall Guidance in November 2018—"o]ur aim is to expand the appropriate use of our mandatory recall authority in cases where we have to intervene quickly to help protect consumers from unsafe products."[13] This guidance was developed with the intention of clarifying the mandatory recall provisions in section 423 of the FD&C Act and shedding light on the Agency's thinking. It addresses matters such as the importance of the mandatory food recall authority, the scope of the food subject to this authority, criteria for a mandatory recall and the process FDA will follow when foods are considered adulterated or misbranded, and the evidence or circumstances that FDA may consider when proceeding with a mandatory food recall.

The Mandatory Food Recall Guidance represents a further step in FDA's efforts to increase the efficiency and transparency of its recall processes, building upon other recall-related draft guidances issued in January and September 2018[14]. As 2019 unfolds, more developments in the recall policy area should be expected, an expression of FDA's continuing commitment to "ensuring that recalls by companies—voluntary or involuntary—are initiated, overseen, and completed promptly and effectively."[15]

III. Updated FDA Standards of Identity for Plant-Based Dairy Alternatives

FDA has issued more than 200 Standard of Identity (SOI) regulations that prescribe the composition of a food, mandatory and optional ingredients, the amounts or relative proportions of each ingredient, and manufacturing methods. Many of these SOIs are outdated, thus, modernizing SOIs is a key component of FDA's Multi-Year Nutrition Innovation Strategy (as we previously highlighted). Modernizing SOIs can also take the form of deregulatory actions, such as the announcement in the Fall 2018 Unified Agenda of Regulatory and Deregulatory Actions that FDA would advance rulemaking to revoke outdated SOIs, including those for French dressing and cherry pie.[16]In addition to modernization efforts, enforcement of certain SOIs, particularly for dairy products, may see an uptick in 2019. As Dr. Gottlieb stated in late September 2018, FDA is "carefully assessing products currently on the market to determine whether any have misleading labels that would prompt us to take action to ensure that consumers are not under the misconception that their plant-based beverage is a dairy product in disguise."[17]

To inform efforts in addressing the increased number of plant-based products marketed as an alternative to dairy products (e.g. almond milk), the Agency issued a request for comments on using the names of dairy foods in the labeling of plant-based products (RFI). The Agency issued this RFI in September 2018, and extended the comment deadline to January 28, 2019.[18] The RFI seeks comment on matters such as consumer perception, use and understanding of plant-based alternatives to their dairy counterparts, market conditions and labeling costs of plant-based products, and how plant-based products and dairy foods play a role in meeting the Dietary Guidelines. Ultimately, FDA intends to use the RFI comments to inform the Agency's development of draft guidance for labeling of plant-based alternatives.[19] As of the date of this publication, more than 5,000 comments have been submitted to the RFI docket.

IV. USDA's Bioengineered Food Disclosure Rule Finalized

On December 21, 2018, USDA's Agricultural Marketing Service (AMS) published its final rule establishing a national bioengineered (BE) food disclosure standard (the NBFDS Rule).[20] For information on the proposed rule and additional background, see our previous post. Below, we highlight key aspects of the final rule of which to be aware and relevant compliance dates.

Definition of a BE Food

The NBFDS Rule's definition of a BE food hews closely to the statutory definition of "bioengineered" and to the proposed rule's definition: "(i) a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; provided that (ii) such food does not contain modified genetic material if the genetic material is not detectable . . ."[21] Note that foods that have undetectable modified genetic material are not BE foods. The proposed rule adds that foods that merely contain an incidental additive at an insignificant level and "does not have any technical or functional effect in the food" would not be considered a BE food.

Disclosure Requirement

Food manufacturers, importers and retailers who package and label food for retail sale or sell bulk items must comply with the NBFDS Rule's disclosure requirements. These requirements apply to BE foods and foods that contain BE food ingredients, such as those included on the list of BE foods in 7 CFR § 66.6.[22] Highly refined foods that do not contain detectable modified genetic material are not considered "bioengineered" and thus, are not subject to mandatory disclosure. However, companies may voluntarily label such products as BE, by stating "derived from bioengineering." AMS expressly prohibited the use of "may contain" disclosures—as such, all disclosures must be affirmative.

Foods that are included on the list of BE foods in 7 CFR § 66.6 are subject to the BE disclosure requirements. Inclusion or exclusion from this list, however, is not outcome determinative; the preamble to the final rule states that the list "does not absolve regulated entities from the requirement to disclose the BE status of food and food ingredients produced with foods not on the list when the regulated entities have actual knowledge that such foods or food ingredients are bioengineered. "[23]

Disclosing the BE status of a Food

The final rule offers several options for regulated entities to disclose the BE status of a food—(1) text disclosure, (2) symbol disclosure, (3) electronic disclosure, and (4) text message disclosure. Small entities may avail themselves of additional disclosure methods; likewise, additional options are available for small packages.

Exemptions

The following foods and entities are not subject to the requirements of the NBFDS Rule and are thus exempt from the disclosure requirements:

- Foods served in restaurants or similar retail food establishments;
- Very small food manufacturers (those with annual receipts of less than $2.5 million);
- Foods "in which no ingredient intentionally contains a [BE] substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient";
- Foods derived from animals are not considered BE merely because they consumed feed produced from, containing or consisting of a BE substance; and
- Food certified under the National Organic Program.

Key Dates

The NBFDS Rule's effective date is February 19, 2019, though compliance is voluntary through December 31, 2021. Starting on January 1, 2020 (the implementation date), all regulated entities (except for small food manufacturers)[24] should commence "identifying the foods that will need to bear a BE disclosure, the records necessary to meet the recordkeeping requirements, and the type of BE disclosure they will use on their products," while small entities can start this process by January 1, 2021. Compliance is mandatory for all regulated entities starting on January 1, 2022.

V. FDA and USDA Shared Jurisdiction of Cell-Cultured Meat Products

Cell-cultured meats gained international attention in 2013, when a burger patty that was derived from animal cell

cultures grown in a laboratory sold for more than $330,000.*25* Cell-cultured, or "lab-grown," meats have been eagerly anticipated by environmental and animal welfare advocates alike. Some estimate that cell-cultured meats may be commercially available in less than five years, and this burgeoning industry has led to a turf battle over whether such products fall under USDA or FDA jurisdiction.

Over the past year, both USDA and FDA have staked their claims to regulating cell-cultured food products.*26* USDA and FDA hosted a joint meeting on cell-cultured products derived from livestock and poultry on October 23-24, 2018.*27*During the public meeting, USDA and FDA each presented their respective regulatory safety frameworks for cell-cultured foods, and solicited public comments on issues related to safety and labeling. Secretary Perdue and Commissioner Gottlieb committed to working together to develop a clear regulatory framework for cell-cultured food products, which made clear "who does what in this arena."*28*

On November 16, 2018, USDA and FDA issued a statement stating that they will "jointly oversee the production of cell-cultured food products derived from livestock and poultry."*29* Under the framework, FDA will oversee cell collection, cell banks, and cell growth and differentiation. Following the cell harvest stage, USDA will then oversee the production and labeling of food products derived from the cells of livestock and poultry. USDA and FDA asserted both that regulation of cell-cultured foods is within their statutory authority and that legislation defining their respective roles is not necessary.

Conclusion

These regulatory developments can greatly impact the business prospects for companies engaged in the manufacture, sale and marketing of conventional food and dietary supplement products in the United States. Our team will continue to monitor these developments and advise you on pathways to comment on FDA and USDA proposals, lobby regarding potential legislation and comply with finalized regulatory guidance and regulations. In the interim, please feel free to contact us with any questions about the topics addressed here.

1 Agriculture Improvement Act of 2018, Pub.L. 115-334.

2 Hemp is defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Id. at Sec. 10113.

3 Id. at Sec. 12619.

4 Statement from FDA Commissioner Scott Gottlieb, MD, on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds, Dec. 20, 2018.

5 Id.

6 Id.

7 In brief, FDA's position is that because CBD and THC are approved active ingredients in FDA-approved drugs or were the subject of publicly acknowledged clinical investigations prior to being marketed in foods or dietary supplements, they may not now be marketed as foods or dietary supplements. See section 301(ll) of the FD&C Act.

8 FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food, Dec. 20, 2018.

9 Note that several trade associations—the American Herbal Products Association (AHPA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the United Natural Products Alliance (UNPA)—have collectively requested a meeting with FDA to discuss a lawful pathway to market for products containing CBD derived from hemp as lawful dietary supplements or foods. *See* Letter from AHPA, CHPA, CRN, and UNPA to FDA Commissioner Scott Gottlieb, MD, Jan. 8, 2019.

10 Food Safety Modernization Act, Pub. L. 111-353, Sec. 206. *See also* 21 USC 350l.

11 Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff, Nov. 2018, at 3, (Mandatory Food Recall Guidance).

12 FDA Orders Mandatory Recall for Kratom Products Due to Risk of Salmonella, Apr. 3, 2018.

13 Statement from FDA Commissioner Scott Gottlieb, MD, on FDA's Effort to Make More Robust Use of Mandatory Recall Authority to Quickly Remove Unsafe Foods From the Market, Nov. 5, 2018.

14 Draft Guidance for Industry and FDA Staff, Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C, Jan. 2018; Draft Guidance for Industry and FDA Staff, Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls, Sept. 2018.

15 Statement from FDA Commissioner Scott Gottlieb, MD, on FDA's Effort to Make More Robust Use of Mandatory Recall Authority to Quickly Remove Unsafe Foods From the Market, Nov. 5, 2018.

16 *See* Unified Agenda of Regulatory and Deregulatory Actions, HHS/FDA, Fall 2018.

17 Statement from FDA Commissioner Scott Gottlieb, MD, on Modernizing Standards of Identity and the Use of Dairy Names for Plant-Based Substitutes, Sept. 27, 2018.

18 Request for Comments, Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, 83 Fed. Reg. 49103, Sept. 28, 2018; Use of the Names of Dairy Foods in the Labeling of Plant-Based Products; Extension of Comment Period, 83 Fed. Reg. 58775, Nov. 21, 2018.

19 Note that in contrast to dairy products, for which longstanding SOI regulations are in place, plant-based products emulating their dairy counterparts are "nonstandardized foods" for which FDA has not established an SOI.

20 National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65814, Dec. 21, 2018.

21 7 CFR § 66.1.

22 The list of BE foods consists of the following items: Alfalfa, apple (Artice varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink-flesh varieties), potato, salmon (AquAdvantage), soybean, squash (summer), and sugarbeet.

23 NBFDS Rule at 65852.

24 Small food manufacturers are those that have at least $2.5 million but less than $10 million in annual receipts.

25 Long-Awaited Lab-Grown Burger Is Unveiled in London, NPR (Aug. 5, 2013).

26 During an April 2018 hearing before the US House of Representatives Committee on Appropriations, USDA Secretary Perdue asserted jurisdiction over cell-cultured meats, stating that "meat and poultry has been the sole purview of the USDA . . . {and} any product that expects to be labeled as meat would come under that same inspection criteria." See FY 2019 Budget Hearing—US Department of Agriculture, US House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (April 18, 2018). Following the hearing, the House Appropriations Committee included language directing USDA to regulate cell-cultured meat products in its fiscal year 2019 Agriculture-FDA Appropriations bill. See Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2019, § 736 (H.R. 5961, 115th Congress). In response, however, on June 15, 2018, FDA Commissioner Gottlieb issued a statement asserting that the FD&C Act gives FDA jurisdiction over cell-cultured foods, as well as "substances used in the manufacture" of these products. Statement from FDA Commissioner Scott Gottlieb, MD, and FDA Deputy Commissioner Anna Abram on Emerging Food Innovation, "Cultured" Food Products, June 15, 2018,. A USDA spokesperson reiterated the USDA's claim of jurisdiction, while expressing willingness to "work with FDA" on the issue. Welcome to the Turf Battle Over Lab-Grown Meat, Politico, June 15, 2018.

27 FSIS and FDA, Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry, 83 Fed. Reg. 46476, Sept. 13, 2018.

28 USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry Meeting Materials, Oct. 23-24, 2018.

29 Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry, Nov. 16, 2018.