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DIETARY SUPPLEMENT LEGAL UPDATE

April 2016

Since passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement industry has grown to more than $35 billion in annual sales. This robust growth of the industry reflects not only increased interest in these products among consumers, but also significant advancements in nutrition and wellness science and new legal and regulatory challenges to appropriately monitor this marketplace. There have been several recent developments on the legal and regulatory issues challenging the dietary supplement industry, both on the federal and state level.

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Voluntary GMO Labeling Bill Fails In Senate; Vermont GMO Law Challenge Pending

The Senate failed to pass legislation that would have created national, voluntary standards for labeling GMOs and precluded bar states from requiring GMO labels. The bill, S. 2609, failed on a 48 to 49 procedural vote. The House passed a bill last year, H.R. 1599, that would block state GMO-labeling requirements and set up a federal GMO-free certification program.

Vermont's GMO law, scheduled to take effect on July 1, requires farmers and food manufacturers who sell their products in Vermont to label foods that have ingredients enhanced by genetic engineering (GE). Act 120 requires certain products with GE ingredients to include a label warning consumers that the products are or may be "produced with genetic engineering." Manufacturers are also precluded from using "natural" or similar words to describe these products.

The Grocery Manufacturers Association and three other groups sued Vermont in federal court to strike down Act 120. In April 2015, the U.S. District Court granted in part and denied in part Vermont's motion to dismiss and denied the plaintiffs' motion for preliminary

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injunction. The association appealed the decision to the U.S. Court of Appeals for the Second Circuit. It argued that the Act 120 is unconstitutional under the First Amendment and that it was error to deny the preliminary injunction to stop the law from taking effect. The Second Circuit held oral argument in the case on October 8. A decision is expected before July.

Senator McCaskill Requests DOJ Records Of Enforcement Actions After Attorney General Lynch Warns On Supplements

On March 29, 2016 Senator Claire McCaskill, ranking minority member of the Committee on Aging, sent a letter to U.S. Attorney General Loretta Lynch requesting a comprehensive list of enforcement actions taken by the Department of Justice (DOJ) related to the dietary supplement industry. The letter, a copy of which is available here, seeks disclosure of cases referred to DOJ by the FDA, FTC or other agencies, including the reason for the referral, the names of the parties, the dates of referral, the status of the referrals and the dates any were resolved. Senator McCaskill has asked DOJ to respond by April 12, 2016.

In recent months, DOJ has become more active in dietary supplement cases. Last Fall, DOJ brought more than 100 civil and criminal cases targeting marketers and manufacturers of dietary supplements, including USPlabs and its executives. In a March 8th video, Attorney General Lynch issued a warning about the use of dietary supplements. She said that "every day millions of Americans are ingesting substances whose safety and efficacy are not guaranteed. Some of these supplements are simply a waste of money, promising results they can't deliver or advertising ingredients that they don't contain, and too often these supplements don't just abuse consumer trust, they also endanger public health." She went on to say that some products contain harmful ingredients and others falsely claim to cure illness.

Attorney General Lynch advised supplement users to visit the FDA, FTC, Department of Defense and U.S. Anti-Doping Agency websites to help make informed choices. She also recommended that consumers consult with their doctor before using a dietary supplement. The video is available here.

Senator Heinrich Asks FDA To Increase Enforcement

Senator Martin Heinrich sent a letter to the new FDA Commissioner, Dr. Robert Califf, requesting increased enforcement in the dietary supplement market and the removal of bad actors causing trouble for the reputable supplement industry. The Senator wrote: "I respectfully ask that you take steps to raise the visibility and enforcement of dietary supplement safety and compliance measures available to the FDA." He went on to ask the FDA to use "existing legal authorities to prevent

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criminals from marketing and manufacturing products that masquerade as dietary supplements. By selling adulterated products under the guise of dietary supplements, these bad actors erode consumer trust in legitimate products and tarnish the credibility of reputable industry members. Consumers deserve to have confidence that their dietary supplements contain legal ingredients properly disclosed on the label."

FTC Reaches Settlement With Four Companies Falsely Promoting Their Personal Care Products as "All Natural" or "100% Natural." Fifth is Charged in Commission Complaint.

Four companies that market skin care products, shampoos, and sunscreens online have agreed to settle claims by the Federal Trade Commission (FTC) that they falsely claimed that their products are "all natural" or "100% natural," despite the fact that they contain synthetic ingredients, including Dimethicone and Phenoxyethanol. The FTC also brought an administrative claim against a fifth personal care company. Under the proposed settlements, the four companies are barred from making similar misrepresentations in the future and must have competent and reliable evidence to substantiate any ingredient-related, environmental, or health claims. In announcing the settlement, Jessica Rich, Director of the FTC's Bureau of Consumer Protection said: "'All natural' or '100 percent natural' means just that -- no artificial ingredients or chemicals." "Companies should take a lesson from these cases." More information about the FTC's announcement is available at here.

California Supreme Court Holds "Organic" Unfair Competition Claim Is Not Preempted By Federal Law

In December 2015, the California Supreme Court ruled that federal law did not preempt a state law unfair competition claim brought against a company that was mislabeling conventionally grown herbs as organic. In *Quesada v. Herb Thyme Farms, Inc.*, the defendant operated multiple herb farms in California. While one of the farms used organic methods and was certified as such, the company also operated conventional farms. During processing, distributing and marketing, the products were mixed together but nevertheless sold with a "fresh organic" label. The class action plaintiff sued for unfair competition and false advertising.

The defendant argued that the case was preempted under the federal Organic Foods Production Act of 1990. Both the trial and intermediate appellate courts agreed, but the California Supreme Court reversed. The Court found that the complaint alleged defendant engaged in fraud by intentionally labeling conventionally grown herbs as organic. The purpose of the Organic Foods Acts was to create a standard for what production methods qualify as organic to prevent fraud. The Court held that nothing in the Act indicates that Congress intended that the enforcement mechanisms it provided would be exclusive. Thus, the state law claim was not preempted.

FDA Sued Over Legality Of Action On GE Salmon

On November 19, 2015, FDA gave its first approval for a genetically engineered animal intended for food, AquAdvantage Salmon, an Atlantic salmon that reaches market size more quickly than non-GE farm-raised salmon. The FDA regulates GE animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act, because the recombinant DNA (rDNA) construct introduced

into the animal meets the definition of a drug. The rDNA introduces a trait that makes the AquAdvantage Salmon grow faster. FDA found the GE salmon met the regulatory requirements for approval, including that the fish is safe to eat. FDA also determined that the AquAdvantage Salmon is as nutritious as food from other non-GE Atlantic salmon and that there are no biologically relevant differences between AquAdvantage Salmon and other farm-raised Atlantic salmon. The FDA imposed strict conditions to contain the fish and prevent their escape and establishment in the environment. The AquAdvantage Salmon may be raised only in land-based, contained hatchery tanks in two specific facilities in Canada and Panama. There must be physical barriers in the tanks and in the plumbing that carries water out of the facilities to prevent the escape of eggs and fish. The AquAdvantage Salmon are reproductively sterile so that even in the highly unlikely event of an escape, they would be unable to interbreed or establish populations in the wild. The approval does not allow AquAdvantage Salmon to be bred or raised in the United States.

On March 30, 2016, 11 groups sued FDA in U.S. District Court for the Northern District of California, alleging that the AquAdvantage decision is illegal because FDA has no jurisdiction to regulate GE animals under the new animal drug provisions of the Food, Drug and Cosmetic Act, failed to fully considering or disclose the alleged environmental and other risks of this decision, and did not follow proper administrative procedures. The case - titled *Institute For Fisheries Resources v. Burwell, et al.*, No. 3:16-cv-1574 - asks the Court to vacate the decision, require FDA to withdraw its assertion of jurisdiction over GE animals, and enjoin FDA from taking further action on the GE salmon application or any other application for commercialization of a genetically engineered food animal until Congress provides explicit statutory authority governing regulation of such products.

FDA Issues Revised Guidance Concerning Dietary Supplements Labeling

On March 7, 2016, the FDA announced revised guidance for industry titled "A Dietary Supplement Labeling Guide: Chapter II. Identity Statement." The revised guidance clarifies that the term "dietary supplement" may be used as the entire statement of identity for a product without other identifying or descriptive terms. In a 2005 guidance - titled "A Dietary Supplement Guide" - the FDA indicated the term "dietary supplement," by itself, could not be considered a statement of identity. The negative response was contrary to the Food, Drug, and Cosmetic Act §§ 201(ff)(2)(C) and 403(s)(2)(B), as well as 21 C.F.R. § 101.3(g), which explicitly requires dietary supplements to be identified by the term "dietary supplement" as a part of the statement of identity, with only some flexibility. A dietary supplement that fails to comply with the requirements of section 403 of the Act may be considered misbranded. Under section 301(a), violations are subject to penalties, including monetary fines and imprisonment. Thus, the revised and clarified guidance is important.

Comments Requested on Label Statements

FDA has invited comments on the information collection provisions of the regulation requiring the manufacturer, packer, or distributor of a dietary supplement to notify the FDA that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act. The notice also invites comment on a new electronic form that allows manufacturers, packers, and distributors of dietary supplements to notify the FDA via FDA's Unified Registration and Listing System (FURLS). Comments are due by May 10, 2016. See comments.

FDA Sends Warning Letters On Acacia Rigidula

FDA sent warning letters to five marketers of dietary supplements containing the botanical Acacia rigidula (A. rigidula), advising them this is a new dietary ingredient (NDI) for which there is insufficient data showing the ingredient is "reasonably expected to be safe." FDA said it considers these supplements adulterated and told the recipients to immediately cease distribution of the supplements. FDA has said A. rigidula was not marketed in the United States before October 1994, is not an approved food additive and is not generally recognized as safe for foods.

FDA also wrote that "the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered." However, it further said an NDI notification for A. rigidula likely would not be approved: "we know of no evidence that would establish that your product is not adulterated."

Organizations Seek FDA's Revocation Of Perchlorate As A Food Additive

A group of organizations, including the Natural Resources Defense Council, has asked the U.S. Court of Appeals Ninth Circuit to order FDA to decide their administrative petition to revoke FDA's approval of perchlorate as a food additive. Perchlorate, used in food packaging, is alleged to be an endocrine-disrupting chemical that interferes with the thyroid gland. The groups petitioned the FDA in 2014 requesting that FDA rescind its approval of perchlorate as a food additive. Under the law, FDA had 180 days to issue an order granting or denying the petition. FDA did not meet the June 29, 2015 deadline and, on March 31, 2016, the groups filed a petition for mandamus with the U.S. Court of Appeals for the Ninth Circuit for an order compelling the FDA to act.

Pom Wonderful Loses False Advertising Case Against Coca-Cola

Pom Wonderful lost a case it brought against Coca-Cola in 2008 under the Lanham Act, a federal trademark statute under which competitors can sue each other for false advertising. Pom accused Coca-Cola of deceiving consumers into believing that a Minute Maid beverage contained mostly blueberry and pomegranate juices; in fact, it contained very little of each. The U.S. Supreme Court had previously ruled that the Federal Food, Drug and Cosmetic Act and the Lanham Act complement each other in the federal regulation of misleading food and beverage labels. "Competitors, in their own interest, may bring Lanham Act claims like Pom's that challenge food and beverage labels that are regulated by the FDCA." On remand to the lower court for trial, Pom sought damages of $78 million from Coca-Cola. However, the jury ruled that Pom had not proved Coca-Cola's labeling was misleading. The product, "Enhanced Pomegranate Blueberry Flavored 100% Juice Blend", contained just 0.5 percent of the named juices. Coca-Cola argued that the label stated merely that the product was "flavored" with pomegranate and blueberry juices.

Chobani Yogurt Labeling Case On Appeal To Ninth Circuit

In May 2012, a suit was filed on behalf of a putative class of people who had purchased Chobani Greek yogurt, alleging that the products were labeled "all natural" but in fact contained artificial ingredients, flavorings, coloring and chemical preservatives. Further, the labels referred to

evaporated cane juice and did not disclose that this is another term for sugar. The District Court dismissed the case, finding that the complaint did not sufficiently allege the plaintiffs were deceived by the term evaporated cane juice. On appeal to the Ninth Circuit, plaintiffs' argued that they had been seeking out yogurt without added sugar. They were misled into buying the Chobani products because the labels did not refer to "sugar" or "syrup." Chobani countered that the labels were accurate under federal regulations because they disclosed the presence of "evaporated cane juice" and the use of "sugar" would be incorrect. The appeal was argued in March 2015 and a decision is pending.

New Jersey Supplement Company Owner Pleads Guilty

The owner of New Jersey dietary supplement companies pleaded guilty in connection with the sale of methamphetamine precursor chemicals, a separate scheme to defraud purchasers of dietary supplements and money laundering. The defendant, David Romeo, admitted that he was a principal of Global Nutrients, Stella Labs and Nutraceuticals. Starting at least as early as 2003, Romeo directed his employees to use cheaper substitutes in place of the dietary ingredients that had actually been ordered by customers, most of whom were other companies engaged in production of dietary supplements.

Romeo admitted that, as part of the scheme, his businesses sold a weight-loss ingredient called "hoodia." Stella Labs and Nutraceuticals represented to consumers that they were selling hoodia that had been sourced from a rare South African plant, Hoodia gordonii. However, the substance being sold was actually manufactured at a facility in China. As part of his plea agreement, Romeo agreed to forfeit more than $1.2 million. Sentencing is scheduled for May 18, 2016.

Pure Green Coffee Companies Enter Into Consent Order

On March 28, 2016, a Middle District of Florida federal judge approved a consent order in *FTC v. NPB Advertising, Inc., et al.*, enjoining Pure Green Coffee manufacturers and promoters from making unsubstantiated weight loss claims. The defendants are enjoined from making any representations that a dietary supplement, food or drug causes weight loss unless the representation is not misleading and is supported by competent and reliable scientific evidence. They had promoted the product saying it could help consumers lose as much as 17 pounds in 12 weeks. They are also barred from misrepresenting a website or publication is an objective news report. They had created deceptive online sites to promote Pure Green Coffee featuring mastheads of actual or apparent news organizations and advertised the product with an unreliable clinical trial.

5-Hour Energy Wins Trademark Infringement Case

A New York district court awarded the manufacturer of 5-Hour Energy drink a judgment of $20 million plus attorneys' fees against companies that allegedly made and sold millions of counterfeit bottles of the energy supplement. In granting summary judgment, the court found that the defendants willfully infringed the 5-Hour Energy trademark. The court also found that the defendants showed a reckless disregard for public health and tried to cover up the counterfeiting.

California Proposes Changes to Prop. 65 Regulations

California's Office of Environmental Health Hazard Assessment (OEHHA), which administers Prop. 65, has provided notice of changes to the regulation. Public comments are due by April 18, 2016. A copy of the proposed changes is available here.