

# DIETARY SUPPLEMENT LEGAL UPDATE



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#### **Table of Contents**

FDA's New Dietary Ingredient Guidance And Patents	4
FDA Issues Final Gras Rule On Food Ingredients	5
FDA Questions Status Of Vinpocetine As A Dietary Supplement	5
DEA Lists Kratom As A Controlled Substance	6
FDA Issues NDI Draft Guidance	6
GMO Labeling Bill Signed Into Law	7
Puerto Rico Secretary Of Health Issues Administrative Order On Dietary Supplements	8
FDA Issues Medical Food Guidance	3
FDA Deeming Regulations Made Final	9
Chobani Yogurt Labeling Appeal Stayed	10
Senator McCaskill Makes Inquiry After Study Shows Dietary Supplements Can Make Chemotherapy Less Effective	11
Update On CBD	11
Summary Of California Supreme Court Proposition 65 Case, Environmental Law Foundation v. Beech–Nut Nutrition Corp	13
Voluntary GMO Labeling Bill Fails In Senate; Vermont GMO Law Challenge Pending	14
Senator McCaskill Requests DOJ Records Of Enforcement Actions After Attorney General Lynch Warns On Supplements	
Senator Heinrich Asks FDA To Increase Enforcement	15
FTC Reaches Settlement With Four Companies Falsely Promoting Their Personal Care Products as "All Natural" or "100% Natural." Fifth is Charged In Commission Complaint	16
California Supreme Court Holds "Organic" Unfair Competition Claim Is Not Preempted By Federal Law	16
FDA Sued Over Legality Of Action On GE Salmon	17
FDA Issues Revised Guidance Concerning Dietary Supplements Labeling	17
Comments Requested On Label Statements	18
FDA Sends Warning Letters On Acacia Rigidula	18
Organizations Seek FDA's Revocation Of Perchlorate As A Food Additive	18
Pom Wonderful Loses False Advertising Case Against Coca-Cola	19
New Jersey Supplement Company Owner Pleads Guilty	19
Pure Green Coffee Companies Enter Into Consent Order	19
5-Hour Energy Wins Trademark Infringement Case	20
California Proposes Changes to Prop. 65 Regulations	20
Government Targets Dietary Supplement Companies And Executives	20
Oregon Attorney General Sues GNC Over Picamilon And BMPEA	22
Bayer Prevails In Contempt Proceeding	23
FDA Dietary Supplement Reorganization Proposed	24
FDA Requests Comments On Use Of "Natural" On Food Labels	24
FDA Finalizes FSMA Rules	24
Proposed Supplemental Rule For Sugar Labeling	25
California Proposition 65 Developments	25

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 among consumers in these products, 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.

#### **FDA'S New Dietary Ingredient Guidance and Patents**

On August 11, 2016, the Food and Drug Administration (FDA) issued a revised draft guidance to improve dietary supplement companies' new dietary ingredient (NDI) premarket safety notifications to the agency. The NDI Guidance raises issues for companies seeking to protect their intellectual property rights, particularly patents and trade secrets.

The Dietary Supplement Health and Education Act (DSHEA) requires the manufacturer or distributor to notify the FDA at least 75 days before beginning to market a dietary supplement that contains a "new dietary ingredient," which is defined as one that was not used in the food supply and marketed in the United States before October 15, 1994. Supplements are considered adulterated if they contain an NDI not used in the food supply and the required notification has not been submitted to the FDA 75 days before marketing. The draft Guidance is available at Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: (http://www.fda.gov/Food/Guidance Regulation/GuidanceDocumentsRegulatory Information/ucm257563.htm)

The Guidance presents challenges for companies that have applied for or obtained patent protection on their supplement product. Patents are available for inventions that are novel and non-obvious. A supplement cannot be patented if it was previously patented, described in a printed publication, or is in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

For patent applications for a dietary ingredient filed prior to October 15, 1994, the dietary ingredients are grandfathered in and are not NDIs. However, any issued patents have likely expired. Patent applications filed prior to June 8, 1995 have a term measured by the longer of 17 years from the issue date of a patent or 20 years from the date of filing.

For patent applications filed after October 15, 1994, however, the NDI Guidance has the potential to directly affect patentability and regulatory compliance. If a company takes the position that an ingredient was in the diet before October 15, 1994, it would avoid regulatory issues because it would not be considered a NDI and there is no need to submit a NDI Notification (NDIN) to FDA. The company, however, may not be able to obtain a patent because the ingredient was "in use" or "on sale" before the priority date claimed by the inventor. But if the company takes the position that the ingredient was not in the diet before October 15, 1994, it could be protected by a patent. It might, however, need to submit a NDIN, subjecting the ingredient to regulatory issues and possible rejection by FDA. This interplay of patent and regulatory questions requires careful and strategic consideration.

#### FDA Issues Final Gras Rule On Food Ingredients

On August 12, 2016, FDA finalized its proposed rule on substances generally recognized as safe (GRAS). It describes the required criteria and scientific evidence that can be used to demonstrate that the use of a substance in human or animal food has GRAS status. The final rule replaces a voluntary GRAS notification procedure used since 2010. Under the final rule, FDA must respond to a GRAS notice filing within 180 days (which may be extended for an additional 90 days).

The rule provides that a substance cannot be classified as GRAS under the conditions of its intended use if the available data and information do not satisfy the safety standard for a food additive under the Food Drug and Cosmetics Act. GRAS requires "common knowledge," throughout the expert scientific community knowledgeable about the safety of substances directly or indirectly added to food, that there is a reasonable certainty that the substance is not harmful. "Common knowledge" can be based on either "scientific procedures" or on experience based on common use of a substance in food prior to January 1, 1958. General recognition of safety through scientific procedures must be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

The final rule is published at Substances Generally Recognized as Safe: (https://www.federal register.gov/documents/2016/08/17/2016-19164/substances-generally-recognized-as-safe)

# FDA Questions Status Of Vinpocetine As A Dietary Supplement

FDA has asked for comment on whether Vinpocetine, widely marketed for improved memory, can be sold as a dietary supplement. In a request for comment, FDA wrote that Vinpocetine is a synthetic compound, derived from vincamine, an alkaloid found in the Vinca minor plant, or tabersonine, an alkaloid found in Voacanga seeds. FDA believes that Vinpocetine does not fall within the definition of "dietary supplement" in the 1994 Dietary

Supplement and Health Education Act because it is not a vitamin, mineral, herb or other botanical, or a concentrate, metabolite, constituent, extract, or combination of any such ingredient. FDA further indicated that Vinpocetine does not qualify as a dietary supplement because it was approved for investigation as a new drug in 1981, substantial clinical investigation of the product had begun, and the existence of the investigation had been publicized.

FDA's position is controversial because Vinpocetine was the subject of five notifications as a new dietary ingredient, going back to 1997. FDA did not object to any of the notifications or the subsequent sale of Vinpocetine as a dietary supplement. Industry invested in the product in reliance on the notifications. If FDA maintains its position, Vinpocetine could no longer be sold.

FDA has requested comments on Vinpocetine by November 7, 2016. A copy of FDA's request for comments is at Request for Comment on the Status of Vinpocetine: (https://www.federal register.gov/documents/2016/09/07/2016-21350/request-for-comment-on-the-status-of-vinpocetine)

#### **DEA Lists Kratom As A Controlled Substance**

On August 30, 2016, the Drug Enforcement Administration (DEA) announced it would list the active materials in the kratom plant as a drug under Schedule I of the Controlled Substances Act. Mitragynine and 7-hydroxymitragynine are found in kratom, which is a tropical tree. The DEA said that Kratom produces opioid-like effects and is often marketed as a legal alternative to controlled substances. In addition, it concluded that kratom has a high potential for abuse and is not accepted for safe medical use. The DEA's notice is available at Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine Into Schedule I: (https://www.federalregister.gov/documents/2016/08/31/2016-20803/schedules-of-controlled-substances-temporary-placement-of-mitragynine-and-7-hydroxymitragynine-into)

#### **FDA Issues NDI Draft Guidance**

On August 11, 2016, the U.S. Food and Drug Administration (FDA) issued a revised draft guidance to improve dietary supplement companies' new dietary ingredient (NDI) premarket safety notifications to the agency.

The Dietary Supplement Health and Education Act (DSHEA) requires the manufacturer or distributor to notify the FDA at least 75 days before beginning to market a dietary supplement that contains a new dietary ingredient (i.e., one that was not marketed in the United States before Oct. 15, 1994), unless the NDI is used in the food supply without chemical alteration. Dietary supplements are considered adulterated if they contain an NDI not used in the food supply and the required notification has not been submitted to the FDA 75 days before marketing. However, the agency has received fewer than 1,000 NDI notifications since DSHEA was passed in 1994.

The initial draft guidance, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," was released in 2011. The FDA has now revised the draft guidance to clarify several important points that were misunderstood or not fully explained, to describe the public health significance of the recommendations, and to request additional comment before publishing a final guidance. Electronic or written comments on the draft guidance are due by October 11, 2016.

The draft Guidance is available here: (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm257563.htm)

#### **GMO Labeling Bill Signed Into Law**

Legislation to create a federal labeling standard for foods with genetically modified organisms and to block states from issuing their own laws passed the House of Representatives and has been signed into law by the President. The bill, S. 764 (https://www.congress.gov/114/bills/ s764/BILLS-114s764enr.pdf), directs the U.S. Department of Agriculture (USDA) to create a national labeling standard that allows food producers to choose how they want to disclose the presence of genetically modified ingredients. Under the legislation, manufacturers will be able to use text, symbols or a QR code that consumers must scan with a smartphone to relay the information. The QR code labeling provision was controversial, with some arguing that it hurt the poor who do not have smartphones.

Under the new law, USDA must begin the process of deciding what exactly food manufacturers will be required to label. It will be up to USDA to define which ingredients count as "genetically modified ingredients" for the purposes of the law. The agency is supposed to complete this process within two years.

The GMO law also will preempt all state-level labeling laws, including Vermont's GMO law, Act 120, which had taken effect on July 1. The state law required 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 the products.

In *Grocery Manufacturers Ass'n v. Sorrell*, plaintiffs sued Vermont to strike down Act 120. In April 2015, the U.S. District Court denied the motion to preliminarily enjoin the law from taking effect. They appealed the decision to the U.S. Court of Appeals for the Second Circuit, which heard oral argument on October 8, 2015. The appellate court's decision was still pending when the President signed the federal GMO law. Based on the preemption provision, the parties to the appeal agreed the case was moot and it was dismissed.

#### Puerto Rico Secretary Of Health Issues Administrative Order On Dietary Supplements

On February 9, 2016, the Puerto Rican Secretary of Health issued Administrative Order No. 346 without any notice and comment period. The Order imposes a regulatory scheme for all distributors of dietary supplements in Puerto Rico. This Administrative Order was effective immediately. The Order requires a burdensome registration that mirrors much of what is already currently filed with the Food and Drug Administration ("FDA") and a \$25 fee for every variation of a supplement by size. Other fees include: (a) manufacturers must file an application and pay a \$500 fee; (b) wholesale and retail distributors must also register and pay a \$100 fee; (c) facilities are subject to inspection and must pay a \$50 fee.

In June, the President signed into law the Puerto Rico Oversight, Management, and Economic Stability Act S. 2328 (https://www.congress.gov/114/bills/s2328/BILLS-114s2328enr.pdf), that would create a fiscal control board to oversee Puerto Rico's budget. Part of the legislation established a Congressional Task Force on Economic Growth in Puerto Rico. The legislation requires that, by December 31, 2016, the Task Force issue a report to the House and Senate regarding, among other things, the economic effect of Order No. 346 or any successor or substantially similar order, rule, or guidance of Puerto Rico.

Senator Orrin Hatch of Utah, a sponsor of DSHEA, will serve as chairman of the eight-member Task Force. The other members appointed by House and Senate leadership are Representatives Tom MacArthur of New Jersey; Sean Duffy of Wisconsin; Nydia Velazquez of New York; and Pedro Pierluisi, of Puerto Rico; and Senators Marco Rubio of Florida; Bob Menendez of New Jersey and Bill Nelson of Florida.

The Task Force recently issued a statement seeking input from stakeholders. Submissions can be made at the Task Force's mailbox at prtaskforce@mail.house.gov. The deadline to respond is September 2, 2016.

#### **FDA Issues Medical Food Guidance**

FDA issued its final guidance on the definition on labeling of medical foods and provides responses to additional questions about the definition and labeling of medical foods, types of diseases and conditions that a medical food could be used to manage, and updates prior responses from the previous edition of the guidance. The "Frequently Asked Questions About Medical Foods; Second Edition" guidance is available at Guidance Documents: (http://www.fda.gov/downloads/Food/GuidanceRegulation/Guidance DocumentsRegulatoryInformation/UCM500094.pdf)

A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C § 360ee(b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." According to the FDA, medical foods are distinguished from the broader category of foods for special

dietary use by the requirement that medical foods be intended to meet distinct nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those foods simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition.

Medical foods do not require pre-market or drug-like approvals, they must be based on sound medical and nutritional principles, and the FDA subjects them to monitoring. The products have active ingredients derived from food products or dietary ingredients that are generally recognized as safe (GRAS) by FDA. The regulations that govern medical foods are summarized in the final guidance.

#### **FDA Deeming Regulations Made Final**

On May 5, 2016, the FDA finalized a rule extending its authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco and pipe tobacco, among others. This rule helps implement the bipartisan Family Smoking Prevention and Tobacco Control Act of 2009 and allows the FDA to improve public health and protect future generations from the dangers of tobacco use through a variety of steps, including restricting the sale of these tobacco products to minors nationwide. The rule deems "tobacco products," including components and parts (in particular e-liquids; tank systems, flavors, and vials that contain e-liquids) but excludes accessories, to be subject to the Food Drug and Cosmetic Act.<sup>[1]</sup>

Before the rule, there was no federal law prohibiting retailers from selling e-cigarettes, hookah tobacco or cigars to people under age 18. The rule changes that with provisions aimed at restricting youth access, which go into effect in 90 days, including:

- Not allowing products to be sold to persons under the age of 18 years (both in person and online);
- Requiring age verification by photo ID;
- Not allowing the selling of covered tobacco products in vending machines (unless in an adult-only facility); and
- Not allowing the distribution of free samples.

The rule also requires manufacturers of all newly-regulated products to show that the products meet the applicable public health standard set forth in the law and receive marketing authorization from the FDA, unless the product was on the market as of February 15, 2007. The tobacco product review process gives the agency the ability to evaluate factors such as ingredients, product design and health risks, as well as their appeal to youth and non-users.

9

<sup>&</sup>lt;sup>[1]</sup>The rule is available at Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act: (https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the)

Under staggered timelines, the FDA expects that manufacturers will continue selling their products for up to two years while they submit – and an additional year while the FDA reviews – a new tobacco product application. The FDA will issue an order granting marketing authorization where appropriate; otherwise, the product will face FDA enforcement.

Other aspects of the regulation include:

- Registering manufacturing establishments and providing product listings to the FDA;
- Reporting ingredients, and harmful and potentially harmful constituents;
- Requiring pre-market review and authorization of new tobacco products by the FDA;
- Placing health warnings on product packages and advertisements; and
- Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by the FDA.

To assist the newly-regulated tobacco industry in complying with the requirements being announced today, the FDA is also publishing several other regulatory documents that provide additional clarity, instructions and/or the FDA's current thinking on issues specific to the newly-regulated products.

#### **Chobani Yogurt Labeling Appeal Stayed**

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 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 U.S. Court of Appeals for 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. However, the Ninth Circuit has now stayed the case until after the FDA completes its proceedings regarding the use of the terms "natural" and "evaporated cane juice" in food labeling. The Court noted that the agency with regulatory authority over the technical and policy questions should address the issue in the first instance.

# Senator McCaskill Makes Inquiry After Study Shows Dietary Supplements Can Make Chemotherapy Less Effective

After a recent study by the University of Minnesota<sup>[2]</sup> found that several widely used botanicals and dietary supplements can interfere with chemotherapy and other treatments for chronic conditions, Senator Claire McCaskill wrote to ten medical associations on May 17, 2016 to find out what guidance they are offering doctors regarding the possible risks associated with the use of supplements by patients being treated for serious medical conditions. Senator McCaskill said that "[t]he fact is that we don't know enough about how dietary supplements interact with cancer treatments or with the treatment of other serious conditions. The lack of consumer protection in the dietary supplement industry has left patients facing life-threatening illnesses even more vulnerable. I can't sit by while their health and safety is compromised just because our regulatory scheme for dietary supplements is flawed."

McCaskill, the ranking Democrat on the Senate Special Committee on Aging, wrote to ten medical associations asking for any policies they have developed for when and how physicians assess dietary supplement use in patients prior to starting cancer treatment. The associations are: the American Medical Association, the American College of Physicians, the American Society of Clinical Oncology, the American Geriatrics Society, the American Cancer Society, the National Medical Association, the American Osteopathic Association, the Gerontological Society of America, the National Hispanic Medical Association, and the American Pharmacists Association.

<sup>[2]</sup> Patients with cancer undergoing chemotherapy: (https://experts.umn.edu/en/publications/dietary-supplement-usage-by-patients-with-cancer-undergoing-chemo)

#### **Update On CBD**

Cannabis plants contain two main cannabinoids: tetrahydrocannabinol (THC) and cannabidiol (CBD). THC produces psychoactive effects and is responsible for the "high" associated with marijuana ingestion. CBD, on the other hand, produces nearly no psychoactive effects but has been desirable for certain uses including treating seizures. Ambiguities related to these products exist in the marketplace for a variety of reasons. Low-THC strains of cannabis plants that are grown can be referred to as industrial hemp. Terms such as CBD, hemp, and industrial hemp are, at times, used interchangeably. Indeed, no federal agency appears to have a strict definition of "hemp" and certain statutes use terms with some inconsistency.

THC is still listed as a Schedule I drug of the Controlled Substances Act (CSA) meaning the federal government believes it to be a dangerous drug with no recognized medical benefit. Any CBD derived from marijuana is considered to be a Schedule I drug. The DEA nonetheless recently eased certain requirements related to the FDA. The updated requirements apply to FDA approved clinical trials, which now allow the DEA to grant waivers to registered researchers to alter the scope of their research under an FDA Investigational New Drug Application (IND). This change streamlines requests to change

the scope of the research or granting access to more CBD. The prior procedure involved multi-level and multi-agency review, which could take a long time. This change should aid in further research into CBD.

With regards to hemp, the CSA definition of marijuana does not include "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." Hemp, which is created from these mature stalks, is thus exempt from DEA regulation. A 2004 case from the Ninth Circuit confirmed this interpretation of the CSA, finding improper the DEA's interpretive rule that considered industrial hemp to be a Schedule I substance under the CSA. Specifically, the court said, "[t]he non-psychoactive hemp in Appellants' products is derived from the "mature stalks" or is "oil and cake made from the seeds" of the Cannabis plant, and therefore fits within the plainly stated exception to the CSA definition of marijuana. Hemp Indus. Ass'n. v. DEA, 357 F.3d 1012, 1017 (9th Cir. 2004).

The DEA nevertheless has the authority to regulate hemp cultivation via restrictions to grow marijuana and the only exemption to this is the Agricultural Act of 2014. Section 7606 of the Act allows an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. § 1001)) or a state department of agriculture to grow or cultivate industrial hemp if "(1) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and (2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or state department of agriculture is located and such research occurs." This Act provides for an actual definition of "industrial hemp," saying "the term 'industrial hemp' means the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Industrial hemp (i.e., low-THC cannabis or material derived from the stalks of mature plants) can thus only be obtained under this exemption or by importing industrial hemp produced outside of the United States. Therefore, this relatively recent Act may further allow for more research into CBD by allowing certain parties to grow industrial hemp under Section 7606.

The DEA will also be reviewing the classification of marijuana as a Schedule I drug in the near future. The DEA received a letter from eight senators that urged the federal government to facilitate research into marijuana's medical benefits to which the DEA responded with this review. While a change in the classification of marijuana will not alter the overall legality of marijuana, hemp or CBD per se, it may increase the ability to conduct testing and research.

With respect to CBD's use as a dietary supplement, the FDA regulates compounds that it considers to be drugs (i.e., when a firm makes a medical claim about a product) but does not regulate dietary supplements. Under the Dietary Supplements Health and Education Act (DSHEA), supplements cannot claim to "diagnose, treat, cure or prevent any disease."

FDA has determined that it considers marijuana to be a drug and not a dietary supplement. The FDA has specifically said:

Based on available evidence, FDA has concluded that cannabidiol products are excluded from the dietary supplement definition under Section 201(ff)(3)(B)(ii) of the FD&C Act. Under that provision, if an article (such as cannabidiol) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for cannabidiol.

Moreover, the FDA recently placed additional pressure on CBD products when it issued warning letters to eight marketers of CBD dietary supplements warning that it considered the CBD products to be illegal and found that these products were making false claims.

Firms have argued that these products were sold as dietary supplements prior to the filing of an IND by GW Research, which could allow CBD products to satisfy the exception mentioned above. This argument is yet to be settled, however. The legality of these products remains complex because of the intersection of state law and federal law coupled with nuances among federal agencies. To best avoid liability, a firm selling any CBD product should first be sure that it is derived from industrial hemp. The surest route to this may be to import industrial hemp produced abroad due to restrictions existing under Section 76066 of the Agricultural Act of 2014. Secondly, to avoid FDA issues, a firm must be sure that its hemp-derived CBD products are not labeled with any medical claims. As time moves on, the status of some of these products may change, which could facilitate additional marketing, but these issues remain a bit murky for now.

#### Summary Of California Supreme Court Proposition 65 Case, Environmental Law Foundation v. Beech-Nut Nutrition Corp.

In 2011, the Environmental Law Foundation (ELF) sued Beech-Nutrition Corporation (Beech-Nut) alleging that Beech-Nut's products contained excessive levels of lead under California's Safe Drinking Water and Toxic Enforcement Act of 1986, which is commonly referred to as Proposition 65. The trial court found that Beech-Nut used an acceptable method to determine lead levels in certain products. ELF then appealed.

Proposition 65 requires that "'[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in [the safe harbor provisions of the statute]". Environmental Law Foundation v. Beech-Nut Nutrition Corp., 235 Cal.App.4th 307, 312 (2015). An accused party can avoid liability under the safe harbor if "'the person responsible can show ... that

the exposure will have *no observable effect* assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical...". *Id.* at 313.

At trial, an accused party must first establish the "no observable effect level" (NOEL). *Id.* To then procure protection under the safe harbor, the party must establish the level of exposure in question and that the level of exposure was 1,000 times below the NOEL. *Id.* The exposure that is 1,000 times below the NOEL is known as the maximum allowable dose level (MADL). *Id.* The issue in this case was the proper determination of the level of exposure based on the level in question. The level in question is the "'chemical concentration of a listed chemical for the exposure in question'". *Id.* at 312-313. The "'level of exposure' is determined by multiplying the level in question ... times the reasonably anticipated rate of exposure for an individual to a given medium." *Id.* at 327.

Both parties submitted expert reports regarding the determination of the level of exposure but these reports used conflicting methods. The experts disagreed as to whether maximum amounts for any given day should be used or whether using averages was more appropriate. See Id. at 314-322. The court considered whether it was appropriate to use averages for analyzing both the amount of lead in multiple product lots and the exposure time period.

The court held that it was acceptable to determine the lead concentration in the products by averaging the concentrations found in multiple "lots" of products. *Id.* at 323-327. The court thus determined that it was not required to evaluate each lot individually. *Id.* To then determine the rate of exposure, a party may also average the exposure over a period of time, instead of using a single day exposure amount. *Id.* at 327-329. This decision makes it easier for parties to establish exposure levels that allow it to qualify for the safe harbor by averaging the concentration of multiple product lots along with averaging exposure over a period of time.

# 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 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: (http://www.mccaskill.senate.gov/imo/media/doc/Final%20DOJ% 20letter.pdf), 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: (http://www.justice.gov/opa/video/national-consumer-protection-week)

#### 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 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 here: (http://www.ftc.gov/news-events/ press-releases/2016/04/four-companies-agree-stop-falsely-promoting-their-personal-care)

# 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: (https://www.regulations.gov/document? D=FDA\_FRDOC\_0001-6461)

#### 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.

#### **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: (http://oehha.ca.gov/proposition-65/crnr/notice-modification-text-proposed-regulation-title-27-california-code-0)

### Government Targets Dietary Supplement Companies and Executives

On November 17, 2015, the federal government announced a series of criminal and civil cases targeting illegal dietary supplement marketing resulting from investigations by the Department of Justice (DOJ), Food and Drug Administration (FDA), Federal Trade Commission (FTC), Department of Defense, Postal Inspection Service, and the U.S. Anti-Doping Agency.

#### 1. Sellers of Jack3d and OxyElite Pro Indicted

DOJ announced the indictment of USPlabs and four of its executives, among others, for selling products including Jack3d and OxyElite Pro. Many of the allegations against USPlabs stem from its claims that the products were made from natural plant extracts when, in fact, they were synthetic chemicals, including some that were toxic to the liver. The case is pending in federal court in Dallas.

The indictment alleges that USPlabs engaged in a conspiracy to import ingredients from China using false certificates of analysis and false labeling and then lied about the source and nature of those ingredients after it put them in its products. USPlabs told some of its retailers and wholesalers that it used natural plant extracts in products when in fact it was using a synthetic stimulant manufactured in a Chinese chemical factory. USPlabs also allegedly sold products without determining whether they would be safe to use. The indictment claims the defendants were aware of studies that linked the products to liver toxicity.

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allegedly sold products without determining whether they would be safe to use. The indictment claims the defendants were aware of studies that linked the products to liver toxicity.

The indictment also alleges that in October 2013, USPlabs and its principals told the FDA that it would stop distributing OxyElite Pro after the product had been implicated in an outbreak of liver injuries. Despite this promise, USPlabs allegedly engaged in an "all-hands-on-deck" effort to sell as much OxyElite Pro as it could as quickly as possible. Also, USPlabs and three individuals were charged with obstruction of an FDA proceeding and conspiracy to commit money laundering.

#### 2. DOJ Civil Cases

DOJ also filed five civil cases seeking injunctive relief against businesses and individuals that allegedly sold supplements as disease cures or were otherwise in violation of the law. Three cases, investigated by FDA and the Postal Inspection Service, allege that the defendants unlawfully sold products as treatments for various diseases including Alzheimer's disease, cancer, and arthritis. The complaints allege that the defendants' conduct defrauded consumers through the sale of unapproved new and misbranded drugs.

In the fourth case, DOJ alleges that the defendants distribute dietary supplements in a manner that does not conform to current good manufacturing practice (cGMP) and that they are making claims about the uses for many of the products that render them unapproved and misbranded drugs. Furthermore, FDA testing revealed that some of defendants' products contain active pharmaceutical ingredients that are not listed on the products' labels, including one ingredient that was withdrawn from the market in 2010 because of safety concerns. The defendants have agreed to be bound by a consent decree of permanent injunction banning them from selling dietary supplements until they come into compliance with the law.

Lastly, DOJ filed suit alleging that dietary supplements sold by the defendants are adulterated because they are not manufactured in accordance with the FDA's cGMP regulations. One of the dietary supplements contains the ingredient 1,3-dimethylamylamine (DMAA), but does not declare DMAA as an ingredient. In addition, the defendants are alleged to have improperly marketed the product as a disease cure.

#### 3. FTC Actions

The government's sweep also included a lawsuit by the FTC to stop a dietary supplement marketer from making misleading claims that its product can help treat and even cure people who are addicted to opiates, including prescription pain medications and heroin. The FTC's complaint alleged that the defendant deceptively claims that its dietary supplement, a "proprietary blend" of herbs and other compounds, alleviates opiate withdrawal symptoms and increases a user's likelihood of overcoming opiate addiction. The FTC alleges that ads for the product are deceptive because they are false or unsubstantiated. The FTC is seeking a court order providing redress and preventing the company from making such claims unless they can be supported by competent and reliable scientific evidence.

The FTC announced two partial settlements against marketers accused of making unsupported claims for weight-loss supplements. In one case, the FTC claimed defendants made false and misleading health and efficacy claims in direct mail ads and on a website for diet pills and cited fake scientific experts studies. Three defendants agreed to settle the charges. The court order requires two defendants to admit liability in the case, bans them from selling weight-loss programs, products, and services, and imposes a \$2.7 million judgment. Another individual agreed not to engage in prohibited deceptive conduct alleged in the complaint and to pay \$1.6 million. Litigation against the remaining defendants continues.

The other settled case involves the FTC's May 2014 complaint against NPB Advertising, Inc. and others for allegedly using false weight-loss claims and fake news websites to market a dietary supplement called Pure Green Coffee, which had been featured on the Dr. Oz Show. The court order bars the defendants from the deceptive acts and practices described in the complaint and imposes a \$30 million judgment that will be suspended upon the sale of certain assets, payment of \$160,800, and the collection and turnover of an additional \$155,760. Litigation against the remaining defendants continues.

Finally, the FTC announced it sent warning letters to 20 unnamed companies that advertise and sell dietary supplements online for weight loss, warning them that FTC staff has reviewed their weight-loss claims and that they could be misleading.

### Oregon Attorney General Sues GNC Over Picamilon And BMPEA

On October 22, 2015, Oregon Attorney General Ellen Rosenblum sued GNC, alleging that it violated Oregon's Unlawful Trade Practices Act by knowingly selling products that contained the ingredients picamilon and beta-methlyphenylethylamine (BMPEA). The lawsuit alleges that both ingredients were "unapproved drugs that may not be lawfully sold in the United States as a dietary supplement."

GNC has said the lawsuit is without merit. In April 2015, the FDA sent warning letters to five companies (but not GNC) that listed BMPEA as a dietary ingredient in dietary supplements. GNC says it did not receive direct notice from FDA concerning BMPEA, but still stopped selling products containing the ingredient when it indirectly learned of FDA's stance. GNC also asserts it only learned of FDA's position on picamilon, created by synthetically combining niacin with gamma-aminobutyric acid (GABA), when Rosenblum filed suit.

In a related development, Senator Claire McCaskill asked ten retailers to voluntarily pull picamilon supplements from store shelves. She had previously asked FDA to determine "whether picamilon is appropriate for sale, and to remove it from store shelves if it is not." FDA has not responded to her inquiry, prompting her request for voluntary removal by the retailers.

#### **Bayer Prevails In Contempt Proceeding**

The Government did not appeal the ruling of U.S. District Court for the District of New Jersey refusing to hold Bayer AG in contempt for the alleged failure to substantiate structure/function claims made for its probiotic supplement marketed to promote digestion.

A 2007 consent order required Bayer to possess "competent and reliable scientific evidence" for all dietary supplement claims. Bayer's product packaging and advertising states that Phillips' Colon Health (PCH) probiotic supplement "Helps Defend Against Occasional Constipation, Diarrhea, Gas and Bloating." When the government began investigating the claims, Bayer submitted 100 scientific papers as evidence of substantiation. It also had evidence of a robust internal process to substantiate claims.

The government based its case not on the DSHEA or regulatory guidance documents, but on the opinion of one doctor, Dr. Laine, who opined that the only way for Bayer to substantiate its PCH claims – or any structure/function claim – would be by conducting one or more drug-like randomized clinical trials (RCTs) on the product. The expert testified that the balance Congress struck in enacting the dietary supplement regulatory regime is irrelevant and should simply be ignored. He said that the "only way" to substantiate claims for drugs and human dietary supplements is to conduct drug-level RCTs, and that scientific evidence from animal, *in vitro*, or genetic studies could never be used to substantiate supplement claims. He also revealed that his analysis did not consider the significant cost of doing RCTs to meet his testing criteria.

The Court rejected that approach and found that Bayer was not required to have drug-level RCTs to substantiate the structure/function claims for PCH and that it would not hold Bayer in contempt because it had a robust internal process to substantiate claims.

The government asserted Bayer made "implied" claims that the probiotic can help cure, prevent and treat constipation, diarrhea, gas and bloating. Judge Linares said such words – prevent, treat and cure – did not transform Bayer's statements into disease claims. He said Bayer's statements were so-called structure/function claims, which DSHEA permits. "Although the words 'prevent, treat and cure' often signal a disease claim, the government has not proven that Bayer advertised PCH to prevent, treat or cure any disease," Judge Linares wrote. "Instead, the government asserts that Bayer advertised PCH to prevent, treat or cure constipation, diarrhea, gas and bloating. These are not diseases, but rather variations of the normal state of health."

Porzio filed two friend of the Court briefs in the case on behalf of the Natural Products Association.

#### **FDA Dietary Supplement Reorganization Proposed**

The Secretary of Health and Human Services recently notified Congress of her desire to elevate FDA's Division of Dietary Supplement Programs to an "Office" status within the Center for Food Safety and Applied Nutrition (CFSAN). The intent of the reorganization is to provide appropriate regulatory attention to the growing industry and increase FDA's enforcement activities and priorities. Several trade groups, including Natural Products Association, support the move because it would enhance the effectiveness of dietary supplement regulation by allowing this new Office to better compete for resources and attention within FDA.

#### FDA Requests Comments On Use of "Natural" On Food Labels

FDA is asking the public to provide comments on the use of the term "natural" in the labeling of human food products. FDA has received three Citizen Petitions asking that it define the term "natural" for use in food labeling and one Citizen Petition asking that the agency prohibit the term "natural" on food labels. FDA has considered the term "natural" to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or added to, a food that would not normally be expected to be in that food. However, this policy was not intended to address either food production methods (such as the use of pesticides) or food processing or manufacturing methods (such as thermal technologies, pasteurization, or irradiation). FDA also did not consider whether the term "natural" should describe any nutritional or other health benefit.

FDA has asked for public comment on a series of specific questions, including:

- Should we define, through rulemaking, the term "natural?" Why or why not?
- Should we prohibit the term "natural" in food labeling? Why or why not?
- If we define the term "natural," what types of food should be allowed to bear the term "natural?"
- What can be done to ensure that consumers have a consistent and accurate understanding of the term "natural" in food labeling to ensure that it is not misleading?

Comments are currently due by February 10, 2016, but that date may be extended.

#### FDA Finalizes FSMA Rules

On November 13, 2015, FDA finalized rules implementing the Food Safety Modernization Act (FSMA) that establish enforceable safety standards for produce farms and make importers accountable for verifying that imported food meets U.S. safety standards. It also issued a rule establishing a program for the accreditation of third-party certification bodies, also known as auditors, to conduct food safety audits of foreign food facilities.

The Produce Safety final rule establishes standards for growing, harvesting, packing, and holding produce that are designed to work effectively for food safety across the wide

diversity of produce farms. The standards in the final rule include requirements for water quality, employee health and hygiene, wild and domesticated animals, biological soil amendments of animal origin (such as compost and manure), and equipment, tools, and buildings.

The Foreign Supplier Verification Programs rule requires food importers to verify that foreign suppliers are producing food in a manner that meets U.S. safety standards and that they are achieving the same level of food safety as domestic farms and food facilities. The final rule requires importers to conduct verification activities (such as audits of a supplier's facility, sampling and testing of food, or a review of the supplier's relevant food safety records) based on risks linked to the imported food and the performance of the foreign supplier.

The FDA also finalized a rule on Accredited Third-Party Certification. It establishes a program for the accreditation of third-party certification bodies (auditors) to conduct food safety audits and to certify that foreign food facilities and food produced by such facilities meet applicable FDA food safety requirements. FDA can require in specific circumstances that a food offered for import be accompanied by a certification from an accredited third-party certification body.

#### **Proposed Supplemental Rule For Sugar Labeling**

On July 27, 2015, FDA issued a Supplemental Proposed Rule for Updating the Nutrition Facts Label that would, among other things, require declaration of the percent daily value (%DV) for added sugars. The percent daily value would be based on the recommendation that the daily intake of calories from added sugars not exceed 10% of total calories. The comment period on the Supplemental Rule is now closed. FDA will consider comments on the original and supplemental proposed rules before issuing a final rule.

#### California Proposition 65 Developments

1. State Attorney General Proposes Regulatory Changes to Curb Lawsuit Abuse

In 2014, businesses paid more than \$29 million in settlements last year related to California Proposition 65. Of that total, \$21 million went for attorney fees and costs. Attorney General Kamala Harris has proposed a series of regulatory changes to Proposition 65 intended to curb frivolous lawsuits. The proposal seeks to ensure that a greater share of civil penalties paid by businesses go to fulfilling the law's purpose of protecting public health. The change proposed by Harris would require private enforcers of the law – mainly environmental and consumer groups – to better define and report how they will spend settlement payments. The rule also proposes to cap "in lieu of penalties" payments paid by businesses, so that a greater share of the fines go to the Office of Environmental Health Hazard Assessment (OEHHA), which administers Proposition 65.

### 2. Proposed Amendment to Lower the Lead (Pb) Maximum Allowed Dose Level in Consumer Products

OEHHA issued another pre-regulatory proposal, drafted in response to a petition by the Center for Environmental Health, a frequent Proposition 65 plaintiff, to amend the safe harbor level for lead. The proposal would lower the lead limit below its current value, which is already below federal actionable levels. In fact, it would lower the maximum allowable dose level (MADL) by 60% from 0.5  $\mu$ g to 0.2  $\mu$ g. If this rule is adopted, additional products would become subject to warning requirements.

#### 3. Proposed Amendment on Use of Arithmetic Mean to Calculate Safe Harbor Levels

OEHHA, which has the authority to adopt regulations for safe harbor levels for listed chemicals, announced that it is considering amending the existing regulation to clarify that the reasonably anticipated rate of intake or exposure to a listed chemical must be calculated as the arithmetic mean of daily intake or exposure for product users. OEHHA provided draft regulatory language and explanatory information for possible amendment.

Geometric means are routinely used to log normal distribution of food intake and exposure assessments. FDA and even OEHHA documents describe the use of geometric means rather than arithmetic means. Limiting the calculation to the arithmetic mean could cause over-warning since arithmetic mean does not account for skewed data and would return higher results. Companies will be forced to label their products with the Proposition 65 warning when there is minimal risk. The proposal would counter an appellate court's ruling in *Environmental Law Foundation v. Beech-Nut Nutrition Corp.*, which held that the geometric mean was more appropriate than the arithmetic mean when calculating the reasonably anticipated rate of intake for average users of food products in that case.



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