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DIETARY SUPPLEMENT LEGAL UPDATE

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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.

For more information on the issues discussed, contact Kevin M. Bell or Richard J. Oparil.

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

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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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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 ACTS ON GENETICALLY ENGINEERED SALMON AND ISSUES GUIDANCE DOCUMENTS

On November 19, 2015, FDA took actions regarding food from genetically engineered (GE) plants and animals. The agency gave its first approval for a GE animal intended for food, AquAdvantage Salmon. FDA also issued two guidance documents for manufacturers who wish to voluntarily label their products as containing ingredients from GE or non-GE sources - a draft guidance on labeling foods derived from Atlantic salmon and a final guidance on foods derived from GE plants.

The FDA approved the application for 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 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.

FDA also published guidance documents on voluntary labeling of food from GE sources. These two documents include a draft guidance on voluntary labeling indicating whether food has or has not been derived from GE Atlantic salmon, and a final guidance on voluntary labeling indicating whether food has or has not been derived from GE plants. These guidance documents provide recommended actions for manufacturers who may wish to voluntarily label their products with information about whether the foods contain ingredients from GE sources.

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 µg to 0.2 µg. 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.