NATURE'S SUNSHINE PRODUCTS, INC.

REGULATORY UPDATE OCTOBER, 2015
VOLUME III, ISSUE III

Through this short newsletter, we strive to provide our Members with a snapshot of the key regulatory issues affecting our industry and, where applicable, the Company's role in those issues. Each quarterly newsletter will focus on some of the major developments in our industry since the prior edition. We encourage you to share this information with those in your successline to whom this information would benefit. As always, if you have questions or would like more detail, please contact a member of the Nature's Sunshine Legal Department. Finally, we welcome your feedback. Please let us know what we can do better. **This is for NSP Members/ Distributors/Managers and not for public dissemination.**

NEW YORK ATTORNEY GENERAL SENDS CEASE AND DESIST LETTERS TO 13 MAKERS OF DEVIL'S CLAW PRODUCT. On September 9, 2015, 14 makers of Devil's Claw supplements were targeted by the New York Attorney General's Office (NYAG). (One company, Nature's Way, had already committed to include DNA testing). The letter demanded that these dietary supplement manufacturers "cease and desist from the sale, distribution, or marketing of adulterated or misbranded 'devil's claw' supplements." Nature's Sunshine received one of the letters. The letters were based on a DNA bar coding study conducted at the New York Botanical Garden. It was alleged that the dietary supplements company's products that were targeted contained a cheaper less desirable species of devil's claw. The various trade groups have all weighed in on the issue. The Council for Responsible Nutrition (CRN) issued a press statement with Mr. Mister stating among other things that, "The companies involved should be permitted to defend their methods of ingredient testing and to justify their use of particular species of botanicals before being declared to be misbranded or adulterated by the New York Attorney General." CRN has also prepared a white paper and various materials which can be found at the following link regarding the NYAG issue. And Natural Product Association (NPA), Dan Fabricant, has issue a news release stating he is available to discuss the NYAGs actions and calling on the FDA to ask the NYAG to release his findings regarding the science. As reported in prior Regulatory Updates, this is not the first time the NYAG has targeted the dietary supplement industry. Mr. Fabricant states, "More than six months have passed since the Attorney General first began this inquiry and two critical issues remain. First, he has yet to make public or subject to peer review the questionable "science" or "research" on which this action is based. Second, he has not pursued prosecutorial actions in either case. We encourage the U.S. Food and Drug Administration and other public health interests to ask the Attorney General to release his findings immediately so they can do the most good for consumer protection in the quickest fashion possible." The American Botanical Council (ABC) in a Press Release states that the, "NY AG focus is too narrow and splitting hairs." **NSP has apprised its top leaders, the board and employees of this issue. NSP Legal and Science are working on the issue and will update as appropriate.**

MULTILEVEL MARKETING COMPANY, VEMMA NUTRITION COMPANY, VEMMA INTERNATIONAL HOLDINGS, INC. (VEMMA), SHUT DOWN BY THE COURT, FOR ALLEGEDLY RUNNING A PYRAMID SCHEME. On August 21, 2015, at the request of the Federal Trade Commission (FTC), the Federal Court temporarily halted business of Vemma, froze their assets and appointed a temporary receiver pending a trial. The action was filed in the United States District Court for the District Court of Arizona. The allegations being made are that (i) Vemma preys on college students and young adults with the promise to get rich quick (income claims), (ii) Vemma is an illegal pyramid scheme and focuses on recruitment rather than retail sales of its

product. To become a Vemma Affiliate (distributor), a consumer must either purchase a $600 Affiliate Pack or personally enroll a Customer or Affiliate. The FTC applied the two-prong test to determine if Vemma was operating a pyramid scheme. The two-prong test consists of "payment by participants of money to the company in return for which they receive (1) the right to sell a product, and (2) the right to receive in return for recruiting other participants into the program rewards for which are unrelated to the sale of product to the ultimate users." The FTC suggests that "the opportunity to earn cash rewards is the primary purpose of Affiliate purchases- the drinks contained in the product packs are merely incidental." The FTC alleges that Vemma satisfied both prongs, the first in that participants were, "required to purchase and Affiliate Pack to earn full rewards under the compensation plan, and Affiliates are strongly encouraged to enroll in the monthly auto-ship program to maintain eligibility for bonuses." The second prong was met by claiming, "Clear emphasis on the program and the opportunity to receive financial freedom though recruitment and enrollment of others" and "when Affiliates earn compensation from Affiliate Pack purchases of their downlines, they are receiving compensation for recruitment by default." Vemma's earnings were more than $200 million in 2013 and 2014. They have operations in the United States as well as 50 other countries. The Direct Selling Association (DSA) has weighed in on this issue and "believe the FTC has not changed or altered their pyramid review analysis." A hearing on the issue was held on September 18, 2015. Federal Court Judge, John Tucci, modified the initial order and replaced the temporary restraining order with a Preliminary Injunction. The judge lifted the freeze on Vemma's assets and removed the receiver and appointed a "monitor" to supervise the court order. Vemma can resume business operations as long as the refrain from doing the following; (1) Paying compensation for recruiting new members, (2) Incentivizing members to purchase goods or services to maintain eligibility for bonuses, (3) Paying any compensation related to the purchase or sale of goods, unless the majority of compensation is derived from sales to or purchase by persons not part of the marketing program; and (4) Selling Affiliate packs or linking Affiliate packs to eligibility for bonuses. The order stated that "the Court concludes that measures less drastic than some of the relief the FTC seeks are available to remedy the harm shown." **NSP Legal will continue to monitor and provide updates on this article.**

MIKE POMPEO, R-KAN., AND G.K. BUTTERFIELD, D-N.C., REINTRODUCE H.R. 1599 "THE SAFE AND ACCURATE FOOD LABELING ACT OF 2015" (SAFLA). On March 25, 2015, The SAFLA was reintroduced. This bill is proposed to replace H.R. 4432 – The Safe and Accurate Food Act of 2014, introduced last year. This legislation, if passed, would help to ensure that American farmers can continue to provide affordable food in the United States and around the world. The SAFLA, would give ultimate authority of genetically modified (GMO) labeling to the FDA, which favors a voluntary approach to this issue. This bill would preempt state laws and define "natural" as containing GMO ingredients. There are currently nearly 30 states with mandatory labeling bills. Pompeo states, "Our goal for this legislation remains to provide clarity and transparency in food labeling, support innovation, and keep food affordable." On July 23, 2015 this Bill passed the House and was received in the Senate. The Bill was read twice in the Senate and referred to the Committee on Agriculture, Nutrition and Forestry. It is said that this Bill will face a tougher fight in the Senate. The Environmental Working Group (EWG), on the same day as the Bill passed the House said, "Today's vote to deny American's the right to know what's in their food and how it's grown was a foregone conclusion. This House was bought and paid for by corporate interests, so it's no surprise that it passed a bill to block states and the FDA from giving consumers basic information about their food." Furthermore, EWG stated, "American's should have the same right as citizens in

64 other countries to know what's in their food and how it's grown." **NSP Legal is continuing to track this legislation and will follow and provide updates.**

PROPOSED RULE ISSUED BY FEDERAL DRUG ADMINISTRATION (FDA) ON HOMEOPATHIC PRODUCT REGULATION. The FDA announced a public hearing to obtain information and comments about the current use of human drug and biological products labeled as homeopathic. The products include prescription drugs and biological products labeled as homeopathic and over-the counter (OTC) drugs labeled as homeopathic. The FDA issued a second extension of the 60 day comment period to November 9, 2015. As a matter of background, the FDA is evaluating its current enforcement policies for drug products labeled as homeopathic from scientific, risk and process perspectives. The FDA was soliciting opinions about whether and how to adjust the current enforcement policies to reflect changes in the homeopathic product marketplace over the last 25 years. One of the main issues is if these products should be regulated by the FDA the same way as pharmaceutical products. At this point, the FDA continues to gather information and has not made a decision on whether to change their regulatory approach. While Nature's Sunshine does not currently sell Homeopathic products, it is important to keep on top of this legislation. **NSP Legal will continue to monitor and provide updates after the comment period is closed.**

NEW YORK BILL S15 - 2015. New York Bill S15 – 2015 was introduced this year. This Bill if passed will require that products labeled as dietary supplements or nutritional supplements carry a label stating that the product has or has not been tested by the United Stated Federal Drug Administration (FDA). This Bill was committed to the rules committee June 25, 2015 after a third reading. If passed, this bill will become law within 180 days of passage. There has not been any movement on this Bill since it was committee to the Rules Committee. **NSP Legal will continue to monitor and provide updates.**

FOUR MAJOR TRADE GROUPS SEND JOINT LETTER TO FEDERAL DRUG ADMINISTRATION (FDA) – REQUESTING ELEVATION OF THE DIVISION OF DIETARY SUPPLEMENT PROGRAMS TO THE STATUS OF "OFFICE." On August 18, 2015, four of the major trade groups, Consumer Healthcare Products Association (CHPA), Council for Responsible Nutrition (CRN), Natural Products Association (NPA) and United Natural Products Alliance (UNPA) sent a joint letter to the FDA requesting that the Division of Dietary Supplements be elevated to the status of "office." They feel this would make issues with the FDA more streamlined for the dietary supplement industry. Loren Israelsen from UNPA states, "We believe this is a clear demonstration of our industry's commitment to supporting an effective and properly staffed regulator, which we will note in future correspondence to the national media who often suggest the DS industry both lacks and resists regulation." As it is too early to provide a link, please see the contents of the letter embedded below:

The Honorable Stephen Ostroff, M.D
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via email: Stephen.Ostroff@fda.hhs.gov

RE: Elevating the Division of Dietary Supplement Programs to an "Office" within CFSAN

Dear Commissioner Ostroff:

On behalf of the trade associations representing the dietary supplement industry—the American Herbal Products Association (AHPA), Consumer Healthcare Products Association (CHPA), Council for Responsible Nutrition (CRN), Natural Products Association (NPA) and United Natural Products Alliance (UNPA)—we write to express collectively our interest in and support for the elevation of the Division of Dietary Supplement Programs (DDSP) to an "Office" status within the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN).

Since DDSP was established within FDA, shortly after the passage of the Dietary Supplement Health and Education Act of 1994, the dietary supplement industry has grown from around $6 billion in annual sales to more than $35 billion in sales in 2014. This robust growth of the industry reflects not only increased interest among consumers in these products, but also significant advancements in the science of nutrition and wellness and new regulatory challenges to appropriately monitor this marketplace. We believe that the elevation of DDSP to an "Office" would provide appropriate regulatory attention to the growing industry and increase FDA's enforcement activities and priorities. In addition, we believe such reorganization would enhance the effectiveness of dietary supplement regulation by allowing this new Office to better compete for resources and attention within the Agency, along with other products under CFSAN's jurisdiction (e.g., cosmetics, medical foods). Such a move would aid in accomplishing FDA's current and long-range goals related to dietary supplements.

Moreover, the industry is deeply concerned about entities—both individuals and companies—who engage in blatant criminal activity by manufacturing and marketing products that masquerade as "dietary supplements" but contain anabolic steroids, active pharmaceutical ingredients (APIs), or analogues of APIs. As you know, our associations have consistently urged FDA to engage in stronger enforcement activities to address bad actors that illegally manufacture and sell misbranded drug products falsely labeled as dietary supplements. We believe that elevating DDSP's status to an Office could help to increase FDA's abilities to take more aggressive enforcement action; better utilize CFSAN's compliance and enforcement resources than it currently does as a "Division" where it competes with other divisions for enforcement priorities within the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS).

Please let anyone of us know if you have questions related to this request and we look forward to your reply.

Best regards,

Scott Melville, President & CEO, Consumer Healthcare Products Association
Steve Mister, President & CEO, Council for Responsible Nutrition
Daniel Fabricant, Ph.D., Executive Director & CEO, Natural Products Association
Loren Israelsen, President, United Natural Products Alliance

cc: Mike Taylor, Deputy Commissioner for Food
Ted Elkin, Deputy Director, CFSAN
Cara Welch, Acting Director, Division of Dietary Supplement Programs
The Honorable Orrin Hatch of Utah
The Honorable Martin Heinrich of New Mexico

NSP Legal will monitor and provide updates of how this letter is received by the FDA, and the outcome of such.

CLASS ACTION LAWSUIT FILED AGAINST SCHIFF NUTRITION INTERNATIONAL, INC. (SCHIFF) OVER MEGARED® CARDIOVASCULAR CLAIM WORDING. On August 11, 2015, Jeffrey Johnston working with Fazio Michiletti LLP, on behalf of himself and others similarly situated filed a class action lawsuit in the California Northern District Court against Schiff and its parent company Reckitt Benckiser Group, LLC. The claim is regarding the wording that Schiff uses on its packaging of its MegaRed product. The Complaint is in regards to the advertising and/or labels that state; "'just one small softgel per day' of MegaRed contains all the omega-3 fatty acids a consumer needs to obtain the promised cardiovascular benefits, including a potential reduction in the risk of coronary heart disease." The Complaint alleges that the effectiveness of the product was overstated. It is further alleged that the packaging states, "may reduce the risk of coronary heart disease." The Food and Drug Administration (FDA) has approved a cardiovascular health claim for omega-3s as follows, "supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease." The Complaint alleges that by just stating "may reduce the risk of coronary heart disease," Schiff left out critical qualifying information in the approved health claim wording. The Complaint also cites a guideline by the American Heart Association (AHA) that recommends that people/patients consume 500 to 1,000 milligrams (mg) of omega-3 fatty acids daily to help combat heart disease. According to the Class action, a single MegaRed capsule, which is the supplements recommended daily dose, only contains 50 mg of Omega-3 fatty acids. The Complaint also alleges that Schiff markets the size of their capsule, which is small in comparison to other fish oil capsules, to have similar health benefits, making it one of the products main advantages over other products. The Class Action complaint accuses Schiff of unjust enrichment, on behalf of a nationwide class; and violations of the California Consumers Legal Remedies Act; California Unfair Competition Law; California False Advertising Law and California Sherman Food, Drug and Cosmetic law, on behalf of the California subclass. The Plaintiffs are seeking an injunction prohibiting Schiff from further misleading advertisements, as well as actual and punitive damages. **It is imperative that claims are legally compliant.**

CALIFORNIA LOOKING AT POSSIBLE CHANGE TO PROPOSITION 65 (PROP 65) LEAD LEVELS. On July 2, 2015, the Center for Environmental Health (CEH), filed a petition with the California Office of Environmental Health Hazard Assessment (OEHHA) asking them to repeal or/or amend the Prop 65 regulation regarding the exposure to lead. They are stating that the existing safe harbor level or Maximum Allowable Dose Level (MADL) for lead of 0.5 microgram per day is "too high to protect Californians from the well-established reproductive effects of lead that can and do occur at levels below 500 micrograms per day." They are also saying that since the court have recently allowed some defendants in Prop 65 actions to average lead exposure

over time, the existing regulation has been interpreted to allow lead exposures of up to 7 micrograms per day. OEHHA scheduled a hearing on this matter for October 9, 2015 in Sacramento. **NSP Legal will update after the hearing.**

DIRECT SELLING ASSOCIATION (DSA) LAUNCHES NEW CODE OF ETHICS EDUCATION CAMPAIGN. The DSA is in the process of launching a new Code of Ethics Education Campaign. The campaign will focus on effectively communicating best practices to the membership and the salesforce. In conjunction with this campaign the DSA board recently approved modifications to the current Code of Ethics. The board has approved modifying areas of the Code of Ethics in areas regarding earnings claims, product claims, inventory and transparency. The new Code of Ethics is scheduled to be effective January 2016. To that end, the new campaign will include the education by way of webinars and fact sheets, a best practices portfolio, a salesforce tool kit and consumer protection fact sheets. **NSP Legal or Distributor Education and Compliance will provide more information on this program, as it is received.**

BAYER DEFEATS FTC IN UNITED STATES V. BAYER CORPORATION. On September 12, 2014 the Department of Justice (DOJ) announced that the Consumer Protection Branch of the Civil Division and the US Attorney's Office for the District of New Jersey with the assistance from the Federal Trade Commission (FTC) had filed a motion to show cause (Motion) as to why Bayer should not be held in civil contempt for violating a 2007 court order, see United States of America v. Bayer Corporation - Order. The 2007 court order prohibited Bayer from making any claim about the efficacy of any dietary supplement, multivitamin or weight-control product unless at the time the claim is made; Bayer possesses "competent and reliable scientific evidence" to support the claim. It is alleged that it's Phillips' Colon Health probiotic supplement product is promoted by Bayer for benefits that are not substantiated by competent and reliable science. The Motion focuses on both express and implied claims. The government claims that "Bayer expressly claims Philips' Colon Health can "defend against" occasional constipation, diarrhea, gas and bloating, and impliedly claims that Phillips' Colon Health prevents, treats and cures constipation, diarrhea, and gas and bloating, even though the company lacks competent and reliable scientific evidence for those claims. An example of an implied claim is one of Bayer's television commercials for Phillips' Colon Health featuring a spokesperson (the 'Colon Lady') emphasizing 'diarrhea, constipation, gas, bloating,' and then a consumer praising 'what a difference Phillips' Colon Health has made. According to Marc Ullman, Ullman, Shapiro and Ullman, Bayer strongly disagrees with the DOJ/FTC decision. Mr. Ullman said he finds it interesting the way the Government has lumped express and implied claims together. He sees some potential vulnerability on the implied claims. The Council for Responsible Nutrition (CRN) has filed an amicus brief in the U.S. District Court of New Jersey, stating that FTC's request would set a precedent that would prohibit the use of most structure/function claims. Additionally, the FTC has requested that Bayer support claims for their Phillip's Colon Health probiotic supplement with randomized, placebo-controlled trials (RCTs). The Natural Products Association (NPA), filed an amicus brief as well in the U.S. District Court of New Jersey, and stated, "If the government was correct in its assertion that such RCTs should be required in all cases, entire shelves at drug stores would become bare." The NPA and CRN both argue that "requiring the same level of substantiation for supplements as for drugs deviates from prior regulatory guidance, contradicts Congress' intent in the Dietary Supplement Health and Education Act (DSHEA) and violates the First Amendment." Judge

Linares stated that the "associations have submitted thorough and informative briefs, which are of assistance to the Court, particularly in considering the implications of the ultimate outcome of this dispute on the entire dietary supplement industry". On October 23, 2014, Judge Jose Linares, in the U.S. District Court for the District of New Jersey, determined that the FTC's case against Bayer would move forward, approving the DOJ's "show cause" motion. On February 18, 2015 the United States sent a letter to Judge Dickson, at the US District Court of New Jersey stating that Bayer has yet to respond to the question of whether they possess competent and reliable scientific evidence that could substantiate the claims made for their colon health product. Both sides obtained experts. Bayer retained a geneticist and microbiologist form the University of Nebraska, Dr. Andrew Benson. Dr. Benson's assertion was that the product was effective and that clinical trials were not necessary. The DOJ retained Dr. Loren Laine, director of clinical research at Yale University School of Medicine. Dr. Laine's position was that a clinical trial was necessary in order for Bayer's claims to have basis and Dr. Frederic Bushman, from Perelman School of Medicine at the University of Pennsylvania, whose position was that Bayer's hypothesis as to the product's efficacy was unfounded. Each side tried to bar the other's expert testimony based on Daubert v. Merrell Dow Pharm. Inc., a 1993 U.S. Supreme Court ruling requiring that expert testimony be based on sufficient facts or data, and be the product of reliable principles and methods reliably applied to the facts of the case. The DOJ contended that Dr. Benson was out of his field of expertise. Bayer claimed that Dr. Laine was not a probiotics expert and that Dr. Bushman lacked experience in relevant areas, didn't properly apply the consent decree's legal standard, and offered noncredible testimony. Judge Linares denied both motions, stating that the DOJ "failed to convince this court" that Dr. Benson's opinions were unreliable or not based on sufficient fact—he has extensive microbiology and genetics experience, and used peer-reviewed publications, including some of his own and in regards to Bayer's motion, Judge Linares said the company "failed to articulate why Dr. Laine's testimony does not meet the flexible standards set forth in Daubert." He said, this case "is not … simply about probiotics and as such, Dr. Laine is not required to be a probiotics expert to be useful to the court," he said. "This case is about whether Bayer was in possession of 'competent and reliable scientific evidence' to substantiate its claims about [Phillips' Colon Health]." The judge also dismissed Bayer's claims that Dr. Bushman didn't properly apply the consent decree's legal standard. Stating, his opinion "is not a legal opinion because that is not what is required of an expert." On February 20, 2015, the United States Chamber of Commerce filed an Amicus Curiae Brief in support of Bayer Corporation, arguing that the Government's proposed substantiation standard is contrary to law, the Government's theory is incompatible with the Dietary Supplement Health Education Act (DSHEA) and that the Government's position raises serious First Amendment issues. In an Order made public on Friday, Judge Linares refused to hold Bayer in contempt for having allegedly violating a 2007 Consent Decree governing how it markets dietary supplements. The spokesman for the FTC declined to comment. Bayer said it was, "pleased with the decision, and that claims about the product were 'fully substantiated' by 'numerous' clinical, animal and genetic studies." The attorney from Sidley Austin representing Bayer, said, the government had been trying to impose a "novel, unlawful standard" on Bayer and that "The government had been seeking to subject dietary supplements to the same gold standard for testing as prescription drugs." Furthermore, he stated that "Bayer has faithfully followed the law, including the FTC's previous guidance." This is a great resolution to this case, **NSP has been following this case as it should set a precedence.**