# NATURE'S SUNSHINE PRODUCTS, INC.

REGULATORY UPDATE OCTOBER – DECEMBER 2015

VOLUME III, ISSUE IV

This brief newsletter is designed 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 previous edition. 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.**

## COURT DECISION MAY PROVIDE LEGAL PATH TO DISPUTE WARNING LETTERS FROM STATE AGS.

State Attorneys General have recently been sending warning letters to various dietary supplement companies, alleging that they are marketing drug-like ingredients in violation of deceptive trade practice state laws. But a recent decision by a court of appeals involving a case against Utah supplement company NiGen and the Texas AG may discourage such letters, and could provide a legal pathway for supplement companies to pursue legal claims against a state agency after receiving warning letters.

NiGen is a Utah-based manufacturer and distributor of the dietary supplements. In December 2011, NiGen brought suit against the Texas Attorney General (AG) Ken Paxton after the AG sent warning letters to NiGen, and retailers CVS, Walgreens, and Wal-Mart, alleging that NiGen's use of the term "hCG" related to one of its products was "false, misleading, or deceptive" in violation of the Texas Deceptive Trade Practices Act. Retailers removed the products from the shelves allegedly resulting in millions of dollars in lost revenue for NiGen.

After a lengthy trial process, the 5th Circuit ruled that NiGen's claims are not barred and that NiGen has standing to sue. **Nature's Sunshine Legal will follow and provide updates on this legislation.**

## OREGON AG ACCUSES RETAILER GNC OF SELLING DRUG-SPIKED DIETARY SUPPLEMENTS.

The Oregon AG has accused GNC of selling thousands of units of workout and fat-burner supplement products that contained unlawful synthetic drugs and/or amphetamines. Internal company records show a key GNC official knew as far back as 2007 the ingredient wasn't natural, the suit alleges, and therefore could not lawfully be included in dietary supplements, which can only contain natural ingredients.

"GNC sells products obtained from third-party vendors that GNC knows or should know contain unlawful and potentially unsafe ingredients," the lawsuit alleges, noting that GNC reviews and pre-approves all labels, packaging and marketing materials for products sold in its store that are made by other companies.

GNC issued a short statement about that time stating: "The claims made by the Oregon Attorney General are without merit and GNC intends to vigorously defend against these allegations. In response to FDA statements regarding the regulatory status of BMPEA and picamilon, GNC promptly took action to remove from sale all products containing those ingredients."

The suit alleges more than 4,000 individual violations of Oregon's Unlawful Trade Practices Act, including failing to disclose that products contained the chemicals and misrepresenting that the products were lawful dietary supplements. Each violation carries a maximum penalty of $25,000. **NSP Legal will continue to monitor this situation and report on outcome.**

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## THE NEW JERSEY ASSEMBLY BILL A449.

The New Jersey Assembly Bill A449 (which is modeled after Federal legislation, H.R.1220) would prohibit pyramid promotional schemes. The bill clarifies what is an illegal pyramid scheme versus what is a legitimate multilevel marketing program.

The DSA supports this proposed legislation as a great tool to both protect consumers and weed out unlawful and fly-by-night pyramid schemes and permit legitimate multilevel marketers to do business. Although, the DSA has been working with the New Jersey Retail Merchants Association in favor of the passage of the bill, it is unlikely the bill will pass through the full Assembly before adjourning for 2015. A new Assembly will be convening in January 2016. There has been no opposition by the public concerning this Bill. **Nature's Sunshine Legal will follow and provide updates on this legislation.**

## DIRECT SELLING DAY AT THE CAPITOL.

On October 28th and 29th, 2015, NSP sent a small delegation to Capitol Hill in Washington DC to participate in the Direct Selling Association event, Direct Selling Day at the Capitol. Adriana Mendizabal, NSP Americas President, led the delegation, along with the participation of Marcole Nebeker from our Events team, and Lynn Ohman from Distributor Education and Compliance. Joining them were 6 of our great distributors, Kirk Bashaw, Sue Clemons, Rhonda Dial, LaDonna Frantz, Annie Johns, and Jennifer Weiss.

The group was able to meet with the leaders of the Direct Selling Association, including DSP President, Joe Mariano. More importantly, they were able to meet with many US Representatives, US Senators, and various members of their support staff, in both group settings and private meetings, where they were able to discuss the value and importance of the direct selling industry, the benefits of being an Independent Distributor, and the strengths of Nature's Sunshine. It was a very productive event, and one that helped make connections and represent the interests of our distributor base and our business model with Congress.

In attendance were representatives from over 30 other direct selling companies, totaling approximately 500 people. Here is a link to the uploaded pictures from the DSA.

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**This information is provided for informational purposes.**

## 4LIFE OPENS MANUFACTURING FACILITY.

On December 1, 2015, the Salt Lake City based 4Life Research USA LLC opens a manufacturing facility in Vineyard, Utah, for the firm's branded antioxidants, brain health, protein and detoxifying products. Raw materials and finished goods will continue to be tested by 4Life scientists in the company's analytical laboratory. **This information is provided for informational purposes.**

## DOJ ENLISTS SUPPORTING CAST AGAINST "BAD ACTORS" ON SUPPLEMENT STAGE.

In the past, the DOJ has pursued companies selling illegal or tainted dietary supplements after receiving whistle

blower complaints under the False Claims Act and/or referrals from the FDA to aid in regulatory compliance. However, the DOJ has recently announced it is planning on taking a more proactive approach to pursuing such companies. Industry trade groups support the DOJ's actions to stop the illegal practices of the noncompliant. **Nature's Sunshine Legal will follow and provide updates on this legislation.**

## FDA UPDATES WEBPAGES TO REDUCE CONFUSION BETWEEN LEGAL DIETARY SUPPLEMENTS AND ILLEGAL DRUG-SPIKED PRODUCTS.

The FDA has recently updated language on several pages of its website to more accurately describe illegal, drug-spiked products and to remove references to these as dietary supplements after the American Herbal Products Association requested the changes. Further, the FDA has launched a new enforcement database to identify companies that fraudulently market products for treatment and prevention of serious diseases. (http://www.fda.gov/ICECI/EnforcementActions/AdvisoryLetters/default.htm

Companies that do not cease illegally marketing products after 30 days of receiving an advisory letter from the FDA will see their name listed on the database together with an advisory letter. These letters posted on the website says the agency reviewed company websites, product labels, catalogs, brochures, flyers, package inserts, audio and video, e-commerce and social media accounts. **This information is provided for informational purposes.**

## NEW OFFICE OF DIETARY SUPPLEMENTS PROGRAM.

On December 21, 2015, the Food and Drug Administration announced the creation of the Office of Dietary Supplements Programs (ODSP). The creation of this new office elevates the Administration's program from its previous status as a division under the Office of Nutrition Labeling and Dietary Supplements. The ODSP will monitor the safety of dietary supplement products by continuing to:

- Take action to remove from the market supplement products that are dangerous to consumers;
- Work with FDA's Center for Drug Evaluation and Research to help remove from the market products falsely labeled as dietary supplements that contain potentially harmful pharmaceutical agents;
- Enforce the dietary supplement good manufacturing practices (GMP) regulation, giving priority to cases in which GMP violations:
- Potentially compromise product safety;
- Fail to ensure product identity, potentially jeopardizing consumer safety; and
- Result in consumer deception, when, for example, manufacturers do not verify the identity of their raw materials.
- Take action against claims in cases involving serious risk of harm to the consumer (such as egregious claims of benefit in treating serious diseases) or widespread economic fraud.

According to Joseph T. Aquilina, Attorney for the DSA, the DSA will continue to engage in outreach to the FDA and monitor the administration's programs and issue updates as developments warrant. **This information is provided for informational purposes.**

**ALKEMIST LABS ROLLING OUT NEXT GENERATION SEQUENCING DNA TESTING.** The FDA has recently updated language on several pages of its website to more accurately describe illegal, drug-spiked products and to remove references to these as dietary supplements after the American Herbal Products Association requested the changes. Further, the FDA has launched a new enforcement database to identify companies that fraudulently market products for treatment and prevention of serious diseases. http://www.fda.gov/ICECI/EnforcementActions/AdvisoryLetters/default.htm

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