

# NATURE'S SUNSHINE PRODUCTS, INC.

REGULATORY UPDATE July – September 2016

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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.**

## **Dietary supplements industry contributes \$122 billion, 750K jobs to US economy**

The US dietary supplements industries contribute over \$120 billion to the US economy, or 0.68% of GDP, says a new report. The report was commissioned at the start of 2016, so that the organization could have it ready for its annual day on the Hill, where more than 60 dietary supplement industry executives from 40 companies will share this information with elected officials. See <http://www.nutraingredients-usa.com/Ingredients/Antioxidants-carotenoids/CRN-Dietary-supplements-industry-contributes-122-billion-750K-jobs-to-US-economy>

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

## **DIRECT SELLING, SMALL BUSINESS AND ECONOMIC EXPERTS AGREE: H.R. 5230 BENEFITS CONSUMERS**

Learn what the experts are saying about H.R. 5230, federal anti-pyramid scheme legislation based on existing state consumer protection statutes and judicial decisions:

- [“Support sensible safeguards for Latino small businesses,” Hector Barreto, \*The Hill\*](#)
- [“Clear Definition on Pyramid Schemes Will Prevent Fraud, Protect Consumers,” Joseph N. Mariano, \*Morning Consult\*](#)
- [“Deconstructing the Pyramids: Salutory Legislation Proposed in H.R. 5230,” Chetan Sanghvi, \*Bloomberg BNA\*](#)

H.R. 5230 isn't a new idea --- it's an idea whose time has come at the federal level. H.R. 5230 will help Americans steer clear of scams by making clear in statute the differences between legitimate behavior and fraud. For more information about H.R. 5230, please visit

<http://www.dsa.org/consumerprotection/consumer-protection-legislation>

## **Updates from CRN's Annual Legal, Regulatory and Compliance Forum on Dietary Supplements**

1. There is major disagreement between the FTC and CRN, particularly as it relates to clinical studies. The upshot is that merely having a claims substantiation file may not be enough to satisfy the FTC if it comes calling AND having a clinical study may not be enough either.
2. The FTC will be focusing very heavily on claims and products related to (i) brain health, (ii) weight loss and (iii) kid's health.
3. The states' attorneys general (or representatives from their offices) that were in attendance all stressed that they talked to one another and that their goal was to ensure consumer safety and integrity. They noted that it was their goal to work with the industry to achieve results rather than to take legal or other action.

4. NAD has a slightly more onerous approach to claims substantiation, putting the onus on the advertiser to support claims made. Several members of the audience felt that the NAD was also harsher than the FTC – initiating more investigations and being quicker to find fault.
5. Real damage may not come from FDA/FTC warning, but from subsequent piling on of AG's and plaintiff class actions.
6. Movement toward registration – either governmental or voluntary. Similar to or somewhat close to the registration scheme in Canada. CRN is developing an online registry for launch by end of 2016 – no cost and will provide basic product information and a copy of product labels.
7. The FDA representative focused on hot button issues the FDA was considering, which included a heavy focus on cGMP and ingredient integrity. He noted specifically the FDA's concern about false/misleading labeling (ingredients not in the product, ingredients not approved for inclusion, etc.) and adulteration.

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### **Industry reaction: What #Brexit means for UK & EU nutrition sectors**

For some companies, especially bigger ones selling in multiple European markets, Brexit creates additional complications. It's paramount that the right inputs are applied to the political process in an effort to secure the best possible trade negotiations as the UK navigates itself out of the EU. See <http://www.nutraingredients-usa.com/Markets/Industry-reaction-What-Brexit-means-for-UK-EU-nutrition-sectors>

**Legal will continue to monitor and provide future updates**

### **Industry bids adieu to Vermont law, welcomes national GMO labeling**

The Grocery Manufacturers Association cheered President Obama's signing of national legislation that will immediately nullify Vermont's GMO labeling mandate and usher in a "new era for transparency in ingredient information for consumers, by requiring disclosure of genetically engineered ingredients for families in every state across the nation," said Pam Bailey, president and CEO of GMA, in a statement. The law will require that certain genetically modified foods be identified as such with words, pictures or a QR code. See <http://supermarketnews.com/laws-regulations/industry-bids-adieu-vermont-law-welcomesnational-gmo-labeling#ixzz4lApvmKbu>

**Legal will continue to monitor and provide future updates**

### **British dieticians issue safe sports supplement guide**

The British Dietetic Association (BDA) has produced a guide to help athletes "from the elite to the exercising public" buy and use sports nutrition products. See <http://www.nutraingredients.com/Markets-and-Trends/British-dieticians-issue-safe-sports-supplement-guide>

**Legal will continue to monitor and provide future updates**

### **Puerto Rico Proposed DS registration law**

You may recall that Puerto Rico had proposed a regulatory requirement on all distributors of supplements, together with a per SKU fee and other registration requirements. As an FYI, the Puerto Rico legislature failed to approve this measure.

**Legal will continue to monitor and provide future updates**

### **What's going on with the NY AG 7?**

The initial investigation launched by NY Attorney General Eric Schneiderman focused on seven herbs- Echinacea, Garlic, Ginko Biloba, Ginseng, Saw Palmetto, St. John's wort and Valerian.

The following is a review to see what's happened with these ingredients. See

[http://www.nutraingredients-usa.com/Markets/What-s-going-on-with-the-NY-AG-7?utm\\_source=copyright&utm\\_medium=OnSite&utm\\_campaign=copyright](http://www.nutraingredients-usa.com/Markets/What-s-going-on-with-the-NY-AG-7?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright)

## **Legal will continue to monitor and provide future updates**

### **Herbalife Settlement with FTC**

After undergoing an FTC investigation for more than two years, Herbalife and the FTC have reached a settlement. As part of the settlement, Herbalife has agreed to pay \$200,000,000 to the FTC to settle consumer issues and to undertake the following actions:

1. Differentiate between discount purchasers and business builders, both in terms of nomenclature and contract;
2. Change their compensation focus from distributor purchases to distributor sales.
3. Revise their income claims, and that of their distributors, to ensure that they are realistic and appropriate. Disclaimers that earnings are not typical, and use of a “confusing and complicated” statement of average income are not acceptable;
4. Track the sales of the products to ensure that distributors buying them for retailing actually do sell the products. The FTC reaffirmed its 10 customer rule and stressed the need for distributor audits;
5. Ensure that at least 2/3 of all compensation to distributors is based on retail sales and only 1/3 or less is based on personal consumption;
6. Ensure that at least 80% of all sales are to end users; and
7. Restrict autoship to preferred customers – business builders are prohibited from using autoship.

Finally, Herbalife agreed to appoint and pay for an independent compliance auditor who, for a period of 7 years, will monitor Herbalife’s business and practices to ensure that it is complying with the settlement order. See [https://www.ftc.gov/news-events/press-releases/2016/07/herbalife-will-restructure-its-multi-level-marketing-operations?utm\\_source=govdelivery](https://www.ftc.gov/news-events/press-releases/2016/07/herbalife-will-restructure-its-multi-level-marketing-operations?utm_source=govdelivery)

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### **World of Aromatherapy Conference**

Oct. 20-23, 2016. Salt Lake City, UT. Convening for an eighth year, the National Association for Holistic Aromatherapy will host a conference on aromatherapy. Over 20 presenters, several workshops, and continuing education hours will be available to attendees. See <http://nahaconference.com/>

**This article is for information only.**

### **Gut–brain axis linked again to obesity in Yale study**

A mechanism of action that may explain how changes to the gut microbiota cause obesity in humans has been discovered by researchers at Yale University. See <http://www.nutraingredients-usa.com/Health/Weight-management/Gut-brain-axis-linked-again-to-obesity-in-Yale-study>

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### **Need For Better Research Grows With Supplements' Popularity – NCCIH**

Continued research on non-vitamin and -mineral products' safety is necessary, says National Center for Complementary and Integrative Health Director Josephine Briggs, and improved studies on their effects on users' health are a scientific priority in the center's strategic plan. See Page 11 of the June 27th Tan Sheet

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### **Shelved Massachusetts bill part of rising tide of attempts to regulate supplements at state level**

A moribund Massachusetts bill that would have restricted the sale of certain dietary supplements is part

and parcel of a rising tide of state bills that affect the industry, according to CRN. See <http://www.nutraingredients-usa.com/Regulation/Shelved-bill-part-of-rising-tide-of-state-regulation>  
**Legal will continue to monitor and provide future updates**

### **CRN talks about the “over fed and under nourished” problem in the US**

There are increasing cases of malnutrition and nutrition deficiencies in a developed country like the US, recent studies report. Duffy MacKay, Sr. VP of Science of the CRN discusses how the dietary supplements industry could assist. See <http://www.nutraingredients-usa.com/Ingredients/Antioxidants-carotenoids/Scurvy-Cretinism-US-is-over-fed-and-under-nourished-expert-says>

**This article is for information only.**

### **What does health & wellness mean to consumers? Nielsen conducts global survey**

US consumers increasingly see non-GMO, natural, organic and clean label claims as a proxy for ‘healthy’ or ‘healthier,’ says Nielsen in a new report\* examining how consumers around the globe are thinking about health and wellness. See <http://www.nutraingredients-usa.com/Markets/What-does-health-wellness-mean-to-consumers-asks-Nielsen>

**This article is for information only.**

### **FOOD VISION USA: Let’s get personal. Your microbiome, your blood sugar and you**

A new study at Israel’s Weizmann Institute suggests a link between an individual’s microbiome and his or her blood sugar reactions to different foods. See <http://www.nutraingredients-usa.com/Ingredients/Probiotics-prebiotics/FOOD-VISION-USA-Your-microbiome-your-blood-sugar-and-you>

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### **Lavender Aromatherapy May Significantly Reduce the Number of Hot Flashes in Menopausal Women**

A randomized clinical trial being conducted by J Chin Med Assoc. has found that the use of lavender aromatherapy significantly reduced the number of hot flashes compared to placebo in menopausal women. See <http://cms.herbalgram.org/herbclip/552/081521-552.html?ts=1474914212&signature=ce787c325cd7f05ce832ef14cc537582>

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