Council for Responsible Nutrition
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November 28, 2016

VIA ELECTRONIC SUBMISSION

Dr. Ana C. Ríus Armendáriz, MD
Secretary of Health
Puerto Rico Department of Health
Centro Médico Norte
Calle Periferal Interior
Bo. Monacillos, Río Piedras, PR

Re: Proposed Regulations for Natural Products / Administrative Order 346 (REVISED)

Dear Dr. Ríus Armendáriz:

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to comment to the Puerto Rico Department of Health (PRDH) in response to its proposed adoption of new regulations with regard to "establishments engaged in the manufacture, storage and distribution of natural products in Puerto Rico."

CRN is the leading trade association for the dietary supplement and functional food industry, representing the manufacturers and ingredient suppliers of national name brands and private label dietary supplements and functional food products. Dietary supplements are regulated as a category of food in the United States and its Territories under the Dietary Supplement Health & Education Act (DSHEA), a portion of the federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 et seq. This law imposes extensive requirements for the manufacturing, development, labeling and marketing of these products in Puerto Rico and throughout the United

[1] The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit www.crnusa.org. Follow us on Twitter @crn_supplements and @wannabewell and on Facebook.

States. And many of our members' products are sold in Puerto Rico by local shopkeepers, drug stores, grocery stores, natural food stores and general merchandise stores, and are relied upon by many Puerto Ricans as part of their healthy regimens for the maintenance of good health.

Background

In February, PRDH issued Administrative Order 346 (AO 346),[2] which required manufacturers and distributors of "natural products" and "dietary supplements" to register with the government and pay fees to the Division of Drugs and Pharmacies at PRDH. Required fees included: registration of every product in any size and concentration, certification of manufacturers and retailers, and inspection of facilities and establishments. If an individual or company failed to comply, penalties and additional fees would apply. The regulation was issued without proper notice an opportunity for comment and generated extensive public opposition from consumers and retailers alike both because of the improper procedure by which it was promulgated and negative effects it would have had on access to safe and beneficial products.

After months of widespread opposition, in early October, PRDH issued a moratorium (Administrative Order 356)[3] on the enforcement of AO 346 and publicly announced that the agency would conduct public hearings with an opportunity for notice and comment rulemaking on this controversial regulation—and followed through on this promise by detailing proposed revisions[4] to AO 346 and convening a hearing on October 13 and October 28, respectively. While CRN and its members welcome this new direction, it did not end the matter or relieve the citizens of Puerto Rico of the potential for limitations on their access to a wide range of lawful dietary supplements. No other State or Territory in the United States restricts dietary supplements in this manner.

These proposed regulations purportedly would be issued under Law No. 81 of March 14, 1912, as amended, Law No. 247 of September 3, 2004, as amended, known as the Puerto Rico Pharmacy Act, Law No. 208 of December 30, 2007, as amended, known as the Regulatory Act

[2] Puerto Rico Department of Health, Administrative Order 346
[3] Puerto Rico Department of Health, Administrative Order 356
[4] Puerto Rico Department of Health, Proposed Regulation of Natural Products

for the Practices of Naturopathic Medicine in Puerto Rico, and Law No. 170 of August 12, 1988, as amended, known as the Uniform Administrative Procedures Act.

Industry Position

Until it is overturned by the Governor or revoked by the Secretary of Health, AO 346—even as it has been redrafted—would still require any manufacturer or marketer involved in the manufacture, distribution or sale of dietary supplements to register and pay fees to PRDH and to retain a representative agent for the products to be allowed on the shelves of retail stores and sold on the island. Not only would the individual or legal entity involved in the activity be require to apply for certification, but the actual products themselves would be subject to product registration with associated fees. It would require a variety of unnecessary, restrictive, and in some cases, duplicative fees for manufacturers, distributors, wholesalers, and retailers who wish to sell legitimate dietary supplements products, already in compliance with federal regulations and laws, on the island.

Intended or not, AO 346 levies additional taxes on manufacturers, distributors and products under the guise of greater industry transparency. The consequence of such action results in higher prices, the burden of which is subsequently shouldered by Puerto Rican citizens. Moreover, companies may decide to withdraw from Puerto Rico, unwilling to shoulder the burden of differing regulatory requirements—detrimental not only to consumers, but also to businesses that provide support services to the industry. In an effort to generate revenue and restructure the Territory's debt, the agency has instead constrained Puerto Rican consumers of jobs and limited resources to invest in their health and wellness.

AO 346 is misguided, but more critically, it was wrongly promulgated without proper statutory authority. AO 346 fails to appreciate that dietary supplements are regulated as a category of food in the United States. The Puerto Rico Pharmacy Act (PRPA)[5,6] requires all drugs (both prescription and nonprescription) and medical devices sold in Puerto Rico to be

[5] Puerto Rico Pharmacy Act (Act 247 of 2004); http://www.oslpr.org/download/en/2004/0247.pdf
[6] Puerto Rico Pharmacy Act (Act 133 of 2013); http://www.oslpr.org/2013-2016/leyes/pdf/ley-133-15-Nov-2013.pdf

registered with PRDH. The PRPA does not even mention "dietary supplement" or "natural product," and thus does not confer any authority on PRDH to register these products. PRDH makes the erroneous assumption that dietary supplement products are in the same regulatory category as prescription and OTC drugs, but they are not—dietary supplements are regulated under the Food Drug and Cosmetic Act (FDCA) as a category of food, not drugs. Indeed, the prior version of AO 346 expressly acknowledged that natural products may come in the form of drugs, foods (including dietary supplements) and cosmetics. Only those labeled as drugs are subject to PRPA. By attempting to add administratively the authority to regulate "natural products" generally, and dietary supplements in particular, PRDH has exceeded the authority provided by the PRPA. In addition, AO 346 was promulgated with no opportunity for notice and comment until concerns about the order were publicly raised on the island and with the Congressional PROMESA task force.

Further, by referencing practices associated within the industry, but that remain wholly unrelated to the proposed regulation (e.g. Regulatory Act for the Practices of Naturopathic Medicine in Puerto Rico[7], for which there is no mention of dietary supplements and outlines certification requirements for Naturopathic Doctors), it becomes apparent that PRDH continues to search for any legal authority to bestow AO 346, regardless of legitimacy. The vast majority of dietary supplements sold in Puerto Rico are sold directly to consumers through a variety of retail outlets without the intervention of a naturopathic doctor or other healthcare practitioner. To attempt to find legislative authority over the vast bulk of dietary supplements by invoking legislative oversight of this profession is disingenuous, to say the least.

While CRN does share the concerns expressed by PRDH about the potential for dietary supplements to be spiked with illegal ingredients, this overly broad and burdensome regulation is not the way to address it. If concerns exist with dietary supplement products being spiked with illegal drugs on the island, PRDH should work collaboratively with FDA to address those concerns. Such behavior (the intentional inclusion of ingredients not listed on the label) is

[7] Regulatory Act for the Practices of Naturopathic Medicine in Puerto Rico (Act 208-1997); http://www.oslpr.org/download/en/1997/0208.pdf

already patently illegal under DSHEA, and subject to criminal and civil prosecution. Virtually all facets of dietary supplement manufacturing, labeling and marketing are covered by extensive regulations issued and enforced by FDA and the Federal Trade Commission (FTC). FDA is charged with inspecting manufacturing facilities, reviewing labeling and monitoring products for safety. FTC pursues deceptive, false and misleading advertising. These laws and regulations apply to every dietary supplement product sold in the United States.

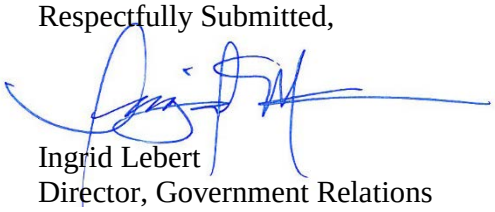
More specifically, the Dietary Supplement Health and Education Act (DSHEA) defines and establishes a federal regulatory structure for dietary supplements, providing FDA with substantial authority to protect consumers and their safety. DSHEA gives FDA multiple tools to remove dietary supplement products from the market if the product, or any of its ingredients, is adulterated or misbranded, poses an imminent hazard to public health or safety, presents a significant or unreasonable risk of illness or injury, contains new ingredients for which there is not adequate evidence of safety, or was manufactured or packaged under conditions that do not comply with good manufacturing practices specific to dietary supplements sold in the United States. Consumers are well protected under this federal regulatory structure. Revised AO 346 would require that all manufactures obtain a Natural Products Manufacturing Certification is duplicative in many respects of federal requirements. Additionally, it would require a Certificate of Analysis issued by a third party laboratory for each product manufactured in Puerto Rico, a burdensome mandate that is likely to drive manufacturing facilities off the island and take jobs and economic benefits with them.

Many Puerto Ricans use dietary supplements, like the multivitamin, protein powders, probiotics and herbal supplements, as part of their dietary regimen. Dietary supplements also include single vitamins, minerals, sports nutrition supplements, weight management products and specialty supplements, like omega 3-fatty acids and glucosamine and chondroitin—all of which would be subject to AO 346. When used properly, these products help promote overall good health and reduce the risk of disease. Requiring registration fees for dietary supplements as well as the retailers who sell them will result in less access and higher costs to consumers.

Conclusion

CRN encourages the Puerto Rico Department of Health to revoke AO 346 as it penalizes an industry that provides health and wellness to consumers, removes economic benefits to the island, remains duplicative of current laws and regulations, casts too broad of a net, carries no statutory authority, and unduly burdens Puerto Rican citizens. CRN appreciates the opportunity for comment on this important matter. Please don't hesitate to contact CRN if you would like additional information on the issues discussed above.

Respectfully Submitted,



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