Dietary Supplement Advertising-April 21, 2017

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State Regulation

CWAG Talks Dietary Supplements

By John Villafranco

At a gathering of the Conference of Western Attorneys General, a panel on "Regulatory Models and Transparency" focused on enforcement against USPlabs as a case study. In 2013, USPlabs was called upon to recall a weight loss supplement that allegedly caused liver damage. The U.S. Department of Justice has since criminally charged the product seller and company executives with violations including conspiracy to import ingredients using falsified documents.

Indiana Attorney General Curtis Hill moderated the panel. Panelists included a member of the Hawaii legislature and representatives from the Council for Responsible Nutrition, the U.S. Pharmacopeial Convention, and a dietary supplement company based in Hawaii.

Panelists discussed what worked in the USPlabs recall – including the post-market surveillance systems that apply to both dietary supplements and OTC drugs. Panelists also took the opportunity to paint a picture of responsible industry and discuss existing laws and voluntary programs focused on compliance and the certification of claims, like "non-GMO." The representative from the Hawaii legislature noted at the end of her discussion that a next frontier for state regulators will be CBD and hemp.

Oregon Attorney General Announces $545,000 Settlement with Retailer

The Oregon AG recently announced a $545,000 settlement with the Vitamin Shoppe over allegations that the store violated Oregon state law by selling dietary supplements containing ingredients that FDA has deemed unsafe or unlawful. The new settlement agreement places significant burdens on the Vitamin Shoppe to monitor developments on ingredient status. The burdens are the same regardless of whether the Vitamin Shoppe sells a product under one of its own brands – or if it sells a product that was manufactured, labeled, and sold to it by a third party vendor.

Under the terms of the agreement, if the Vitamin Shoppe "receives or learns of" a "written notice" from FDA that an ingredient may be unsafe or unlawful, it must "take immediate action to suspend the sale of such products or products known to contain the ingredients." If the Vitamin Shoppe becomes aware of any other "public announcement, warning, alert, publication, notice, or report" suggesting that the U.S. government, Australia, Canada, Britain, or the EU might consider a dietary ingredient unsafe or unlawful under the FDCA, then the Vitamin Shoppe must conduct a "reasonable due diligence review," which may result in a decision not to sell any products containing the ingredient.

This settlement is notable for at least two reasons:

- It identifies FDA warning letters sent to the Vitamin Shoppe or anyone else as "written notice" that FDA has deemed an ingredient unsafe or unlawful. Warning letters, however, state only allegations and are not considered "guidance" under FDA's rule on "good guidance practices."
- Well after a warning letter is issued, the lawfulness of a particular dietary ingredient can be the

subject of much ongoing debate, and even the FDA's official guidance document on ingredient status remains in flux after years of debate.

The settlement represents an aggressive stance by Oregon on a retailer's liability for product formulation and labeling by third parties. As we've discussed before, there isn't a whole lot of precedent for regulators going after the retailer, rather than the product seller.

The Oregon Attorney General is currently in litigation against another retailer over similar allegations related to the legal status and safety of a dietary ingredient.

Class Actions

ConsumerLab.com Fueling Class Actions?

By John Villafranco

A multivitamin seller is facing a consumer class action over allegations that its vitamin B product contains more than two times the amount of folic acid than what is declared on product labels. In the complaint filed in March, plaintiffs also allege that the amount of folic acid exceeds the tolerable upper limit set by the Institute of Medicine. Testing results attached to the complaint, however, provide no details on the type of testing or sampling method used.

In February, ConsumerLab.com began offering for sale "tests of 50 B-complex and single B vitamin supplements." It claimed that its tests "showed that 3 products contained much more of one or more B vitamins than listed" and that "[i]n fact, it was discovered that taking a popular B-complex would cause you to unexpectedly get 50% more than the tolerable upper intake level of folate." The product being targeted in the class action is one of the products ConsumerLab.com said that it tested.

FDA Developments

FDA Wins Some, Loses Some in Litigation with Hi-Tech

A federal district court in Georgia heard motions for summary judgment from both sides in a case in which FDA sought seizure and forfeiture of Hi-Tech Pharmaceuticals, Inc.'s DMAA products. The court had to determine if DMAA is properly a "dietary ingredient," and if not, is it nonetheless legally used as a food ingredient that is "generally recognized as safe" (GRAS).

The court found both that DMAA is not a dietary ingredient and not GRAS. Thus, it held that the Hi-Tech products were subject to seizure and forfeiture. However, in granting this relief to FDA, the court struck a blow to a controversial part of FDA's current draft guidance on new dietary ingredients (NDIs).

The FDCA, as amended by DSHEA, provides that, among other substances, an "herb" or "botanical" is properly a "dietary ingredient" that may be used in a dietary supplement. However, in its NDI guidance, FDA took the position that "a substance that has been synthesized in a laboratory or factory" can never qualify as a dietary ingredient by virtue of being an "herb" or a "botanical." The Georgia court rejected this narrow interpretation of an "herb" or "botanical."

The court found that, in enacting the relevant FDCA provisions, Congress likely intended a synthesized substance to be properly considered an herb or botanical as long as there is "at least some history of the substance in question having been extracted in usable quantities from a plant or plant-like organism." The court noted that if the law were interpreted otherwise "growing popularity of a substance in a certain plant might endanger that plant's existence if manufacturers were not permitted to synthesize the substance." It also noted that "chemical synthesis is often more economically efficient than extracting a particular compound from a plant."

The court found that although Hi-Tech "presented fairly substantial evidence that trace amounts of DMAA ha[d] been found in a species of geranium plant," it appeared that "no one ha[d] ever extracted DMAA from geraniums for any commercial, medicinal or other purpose."

An appeal to the Eleventh Circuit is likely. It should be noted that even without this case potentially

broadening the realm of “herbs” or “botanicals,” the FDA’s current NDI guidance contains another route whereby a synthetic herb or botanical still might be a dietary ingredient. The guidance acknowledges that if such a substance has been used as an ingredient in the conventional food supply, it may properly be a “dietary substance” that counts as a dietary ingredient under a separate part of the “dietary ingredient” definition.

NAD Cases

NAD Gives Bill of Good Health to Dietary Supplement Immunity Claims

The National Advertising Division of the Better Business Bureaus, a self-regulatory body that polices national advertising, recently gave an a-OK to certain dietary supplement immunity claims. The action was initiated under NAD’s partnership with the Council for Responsible Nutrition against dietary supplement maker Olly Public Benefit Corporation. CRN requested that NAD determine whether Olly had a reasonable basis for the message that its Kids Mighty Immunity product helps support immune health. In particular, NAD assessed four immunity-related claims made on the product website:

- “Formulated to help support little immune systems in the biggest way to help keep kids healthy and happy year-round.”
- “Wellmune. These beta glucans support immune health by helping to promote built-in cellular defense mechanisms.”
- “Elderberry. Respect your elders – this super food has been used for centuries to support the immune systems.”
- “Zinc. An essential mineral that helps keep immune cells functioning in tip-top shape.”

In support of its general immunity message, Olly argued that the product is a good or excellent source of vitamins C, D, and zinc and also contains Wellmune beta glucan yeast. The advertiser presented studies and literature explaining the support roles played by vitamin C, vitamin D, and zinc in the immune system. This evidence indicated that the nutrients – when taken in sufficient doses – “help form a physical and chemical barrier to keep out pathogens, and also support specialized adaptive immune system cells that work as part of the body’s natural processes to eliminate pathogens.” NAD found that this data was sufficient, and Olly did not need to present a clinical study on its product, because the context of the webpage and the product packaging conveyed the message that these claims were based on the supplement’s individual ingredients and not testing of the final product.

In addition, Olly provided evidence in both adults and children demonstrating that, after oral digestion, Wellmune is bioavailable and binds to immune cells. NAD found this was a reasonable basis for the Wellmune claim. Likewise, NAD found that the elderberry claim, supported by historical accounts citing elderberry for immune support, was sufficiently limited.

Importantly, NAD appreciated that the advertiser did not make any express or implied claims regarding the common cold or other illnesses and avoided imagery that implied cold prevention or cure, such as depictions of sick children, worried parents, or visits with health care professionals. It noted that evidence presented in other NAD proceedings failed to show a relationship between regular vitamin C supplementation and the reduction in the incidence of colds.

We have seen other examples of cases where immunity claims for foods and dietary supplements have been problematic for companies. However, as shown in this NAD matter, it is possible to effectively tailor claims to the available evidence so that they withstand regulatory scrutiny.

Brain Claims Referred to FTC

The Council for Responsible Nutrition (“CRN”) filed an NAD challenge against the makers of Adderin

dietary supplements. CRN questioned certain claims including the following:

- “After 7 years Harvard scientists finally break new ground and usher in the future of brain science with invention of new smart drug that increases IQ, memory and focus up to 100%.”
- “Forbes broke the news first and uncovered that Adderin raises levels of focus and performance every day by 300%.”
- “Adderin has been clinically proven to Sky-rocket concentration by 312%[;] Improve creative thinking; Boost energy[;] Enhance memory recall[;] Increase IQ scores by 77%.”

The NAD stated that after “repeated attempts to engage the advertisers in the self-regulatory process,” it referred the matter to the FTC.