Dietary Supplement Advertising-March 7, 2016

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Please find below the second edition of our monthly newsletter specifically for our clients marketing dietary supplements. We hope this helps you stay out in front of regulatory challenges.

PROP 65

Proposition 65 Compliance May Get Even More Cumbersome and Unpredictable

BY JOE GREEN

California's "Proposition 65," the much-criticized law that requires prolific warnings of potential exposure to chemicals and fuels copious lawsuits by private citizen groups, is poised to undergo fundamental changes that are likely to make compliance more burdensome. The state's Office of Environmental Health Hazard Assessment ("OEHHA") is considering comments received last month on its latest proposal to overhaul the regulations governing Proposition 65 warning label requirements.

For marketers of dietary supplements, the proposed amendments do not address, and in fact will exacerbate, confusion stemming from inconsistencies between the text of Proposition 65 warnings and the labeling determinations and contaminant assessments in FDA regulation of these products. The proposal would require more specificity in the Proposition 65 warning text that must accompany food products, including dietary supplements. To be compliant, supplements would have to bear the word "WARNING" in bold text in a font no smaller than the largest type size used for other consumer information on the product. The following statement would be required: "Consuming this product can expose you to [name of one or more chemicals], a chemical [or chemicals] known to the State of California to cause [cancer, birth defects, or other reproductive harm]." Finally, the warning must include reference to a new Proposition 65 website where consumers

can find additional information about the chemical(s) in the product and potential exposures: “For more information go to www.P65Warnings.ca.gov/food.” The proposed revised warning text is more detailed and lengthy than the current standard warning, thereby exacerbating space limitations for products, like dietary supplements, that are typically marketed in small packages.

While OEHHA originally proposed to require identification of a “dirty dozen” list of chemicals that would have had to be disclosed in the warning, the new proposal requires naming “one or more chemicals.” The ambiguity of the provision – e.g., is naming one chemical sufficient even if multiple are contained in a product? how to choose which one? – makes it ripe as an issue for a plaintiff to challenge the sufficiency of a warning.

Another significant change is that the proposed new warning replaces the existing “may contain” language with the statement that the product “can expose” the consumer to a listed chemical. That change fails to recognize that, for dietary supplements and other food products, often the chemical for which a warning is required (e.g., lead) is naturally occurring and highly variable in terms of its presence and potential quantity. Accordingly, the “may contain” statement is more accurate and allows flexibility in describing the potential exposure to listed chemicals. This raises perhaps the most important Proposition 65 issue for dietary supplements: the exemption for “naturally occurring” chemicals in food products. Unfortunately, OEHHA has yet to act on industry requests to clarify the exemption, which has proved burdensome to satisfy and a common aspect of litigation in this area.

The proposed amendments include several other provisions worth noting:

- Replaces the mandate to provide a warning “prior to exposure” with a requirement to provide the warning “prior to or during the purchase of the product.”
- Internet purchases: Specific regulatory text is proposed to address warnings provided for internet purchases. The proposal would require that the warning be provided by a clearly marked hyperlink using the word “WARNING” on the product display page, or otherwise be prominently displayed before the purchase is complete.
- Warnings must be provided in foreign languages if the

product labeling contains information in these languages.

- Clarifies when retailers may be held responsible for providing product exposure warnings. These provisions respond to a statutory mandate to minimize burdens on retailers, and in short, require that the manufacturer, producer, packager, importer, or distributor is responsible for adding the warning to a product label or providing a written notice to the retailer regarding the required warning for the product. The responsibility for providing a warning falls on the retailer only under certain conditions, such as when the retailer receives warning information and materials from a supplier and fails to post them.

In a separate rulemaking, OEHHA has finalized a regulation for developing a new Proposition 65 website, to which reference must be made in warnings as noted above. This regulation provides OEHHA authority to require companies to submit information related to a chemical for which a warning is given within 90 days of request. That information can include: chemical identity; concentration and location of the chemical(s) in a product; anticipated routes or pathways of exposure; and estimated levels of exposure to the chemical(s).

FDA DEVELOPMENTS

FDA Targets CBD, Social Media

Last February, FDA issued three warning letters to companies marketing cannabidiol (CBD) products as dietary supplements. FDA reviewed the companies' websites and concluded that claims that CBD products could treat post-traumatic stress disorder, lupus, cancer, and other conditions rendered the products unapproved new drugs.

This February, FDA again turned its attention to CBD products, issuing eight new warning letters. For the first time in an enforcement context, FDA contended that CBD products fail to meet the FDCA definition of a "dietary supplement." The agency explained as follows:

> FDA has concluded that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if a substance (such as CBD) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or a conventional food before the new drug investigations were authorized;

however, based on available evidence, FDA has concluded that this is not the case for CBD.

The existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 C.F.R. § 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

The cited portion of the "dietary supplement" definition is discussed in FDA's controversial 2011 draft guidance on new dietary ingredients. In 2012, FDA committed to revising that guidance. Revised guidance has yet to be released. In each of the new warning letters, FDA also again identified claims that it believed rendered products unapproved new drugs. This time, however, identified claims were drawn from not only company websites, but also product descriptions on Etsy and company posts on Facebook, Twitter, and Pinterest. We discussed FDA and FTC regulation of social media in an article published in Nutritional Outlook. In general, regulators treat social media posts by companies the same as any other labeling or advertising. Regulators may treat posts by consumers like labeling or advertising where a company "likes," comments on, or republishes a post.

New SECG on Omega-3 Nutrient Content Claims

The FDA recently issued a small entity compliance guide (SECG) for its final rule on nutrient content claims for omega-3 fatty acids. The SECG reiterates that, after several seafood processors and ingredient suppliers filed notifications of omega-3 fatty acid claims, FDA reviewed the underlying evidence and decided to allow several claims for ALA, but prohibit many other claims. The following are the allowed ALA claims.

- "High" for ALA (must provide at least 320 mg/serving)
- "Good Source" for ALA (must provide at least 160 mg/serving)
- "More" for ALA (must provide at least 160 mg/serving more than reference food)

FDA rejected "high" claims for EPA, DHA, and a combination of EPA and DHA. It also rejected ALA claims that were based on a different daily value calculation than the allowed claims.

In the past year, the FDA has issued four warning letters alleging that companies used unauthorized nutrient content claims for omega-3 fatty acids. Two letters were to sellers of fish products. One was to a company selling chia waffle and pancake mix. The fourth letter was to a company

selling macaroons.

NAD CASES

The Road to Referral to the FTC

After involvement of the FTC, we appear to be approaching the conclusion of a nearly-three-year battle between the NAD and New Nordic USA, Inc., a company that markets a dietary supplement, Hair Volume. In 2013, as part of its routine monitoring, the NAD inquired about claims for the product. *See New Nordic USA, Inc.*, NAD Case Report #5606 (June 24, 2013). The challenged advertising included a testimonial by a woman named Maya who is pictured with a full head of hair. Maya laments that her hair had been rapidly thinning and says that she had accepted her hair loss as inevitable in light of her mother's early hair loss. She explains, however, that after trying shampoos and other treatments, she learned about the "importance of nutrition for healthy hair" and made the decision to focus on "the inside rather than the outside." Other claims for Hair Volume included, "Thousands of people have already experienced the benefits of Hair Volume, which has made it the world's leading hair tablet" and "[Hair Volume] is a unique innovation and reinvention of the old hair, skin and nail tablet."

The NAD determined that the advertising reasonably communicated an unsubstantiated implied message that Hair Volume would reverse balding, even genetic pattern baldness in women, and restore full and thick hair. New Nordic had not conducted product testing on Hair Volume, which contains zinc and biotin, among other ingredients. Rather, New Nordic presented studies and abstracts about the potential benefits of zinc and biotin. The NAD found the studies to be insufficiently reliable to demonstrate that the ingredients, in the amounts in found in the product, provided the promised benefits. The NAD recommended that New Nordic discontinue most of the challenged claims. In its advertiser statement, New Nordic said it understood what the NAD was recommending and although it felt it had some substantiation from the clinical studies of the ingredients, the company wished to work with the NAD.

Six months after the decision, the NAD contacted the company again after determining that several of the challenged claims were still on New Nordic's website. New Nordic agreed to remove the claims. Months after that incident, the NAD determined that two print advertisements did not comply with NAD's recommendations. New Nordic again agreed to remove the claims.

In December 2014, the NAD brought a third compliance proceeding. This time it alleged that the "Maya" testimonial was still appearing in a national magazine. Once again, New Nordic agreed to discontinue the claims. The final straw for the NAD was when it determined that the "Maya" testimonial appeared yet again in a national magazine. In September 2015, the NAD referred the matter to the FTC.

In January of this year, the FTC's Division of Advertising Practices issued a letter

stating that New Nordic “now intends to cooperate with NAD’s inquiry” and will soon contact the NAD to “reengage in the NAD self-regulatory process.” As a result, the letter concluded that no additional FTC action was warranted at this time.

In general after two or three compliance inquiries, the NAD will refer a case file to the FTC if it determines that an advertiser has failed to comply with its recommendations. With the FTC’s ability to conduct a full-blown investigation and demand monetary redress for advertising violations (usually to the tune of full revenue from sales), FTC attention be devastating. Class actions that typically follow an FTC order add to the pain. Although there are sometimes exceptions, the road to FTC referral is usually best left untraveled.

All the Ways an NAD Case Can Close

The NAD recently closed two cases on dietary supplement claims. These two cases illustrate two of the three different ways an NAD case might close. The first case involved advertising for Cellfood. *See NuScience Corp.*, NAD Case No. 5931 (Feb. 2016). The NAD, as a part of its routine monitoring, had inquired about claims, such as the following: “By adding 24 drops of Cellfood to your water bottle each day, you’ll clean and detoxify, help to eliminate free radicals and bring oxygen, hydrogen and plant nutrients into your body.” The advertiser, in response to the inquiry, informed the NAD that it had permanently discontinued the identified claims prior to the initiation of the case. Thus, according to its rules, the NAD closed the case entirely. This means that no compliance proceedings will be possible, although an entirely new case could be filed based on the same advertising claims.

The second closed case involved advertising for JuniorSlim, a children’s weight loss product. S*ee Silver Star Brands*, NAD Case No. 5918 (Jan. 2016). The NAD had inquired about claims, such as, “Addresses the tendency to comfort eat” and “Maintains healthy energy levels through nutrient absorption.” During the pendency of the case, the advertiser committed to discontinuing the claims. In this instance, although the NAD did not issue a formal decision, it stated that it would treat the claims, “for compliance purposes, as though the NAD recommended their discontinuance and the advertiser agreed to comply.” This is the manner in which the NAD routinely proceeds if an advertiser discontinues claims during, rather than before, a case begins. It means that the NAD could later bring a compliance review.

The NAD issued revised procedural rules on February 1, 2016. A new provision in the rules creates a third way for an NAD case to close. The parties may reach a settlement and agree to notify the NAD in writing of their consent to close. Similar to the situation where claims are discontinued prior to initiation of a case, a case closed on consent of the parties will be closed entirely, without the opportunity for compliance review. However, once again, nothing in rules bars the filing of an entirely new case if the advertiser continues to disseminate the same claims. A new filing fee would be required, though, for entities other than the NAD. Challengers who agree to consent to closure are well-advised to consider requiring, as part of a settlement agreement, that the advertiser pay

the new filing fee should a new challenge on the same claims become necessary.

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