Dietary Supplement Advertising-April 11, 2016

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

FTC DEVELOPMENTS

"Made in the USA" Enforcement: FTC Targets All Sorts of Products, Files Suit in One Case

The FTC recently filed suit against a glue maker over "Made in the USA" claims. This development is notable given that the FTC regularly investigates U.S. origin claims, but rarely initiates litigation in the area. The recent lawsuit likely involves a company that was unwilling to revise its advertising.

Typically, during the course of an investigation into U.S. origin clams, the company will agree to modify its claims, and the FTC will then issue a closing letter. Since January 2015, the FTC has issued 33 such closing letters, which averages to about two per month. These letters indicate not only that the FTC remains active in the area, but also that it has targeted claims for an extremely wide variety of products – specifically, watches, computers, televisions, cleaning products, cookware, bakeware, lanyards, battery chargers, standing desks, regular desks, artificial grass, tape, magnetic harmonica holders, food service sinks, security systems, snow blowers, disposable butane lighters, laser sights for firearms, deck screws and kits, floor and wall tile, lumber, auto parts, a cleaning device for cloth diapers, skateboard trucks, and pet products.

The FTC has not investigated U.S. origin claims for any dietary supplements in recent years, but this wide net cast over all manner of products provides little comfort. If magnetic harmonica holders made it in, who's to say a dietary supplement won't be next.

For "Made in the USA" claims, the FTC follows a stringent and

often-complex standard requiring that "all or virtually all" of a product is made in the United States. A challenge for dietary supplements is that, in the past, processing like mixing with other ingredients or removing impurities has not been considered a "substantial transformation" adequate to overcome the use of foreign raw dietary ingredients. Companies selling dietary supplements and conventional foods have faced litigation (or the threat of litigation) by private actors based on California's law on U.S. origin claims. *See, e.g., Alaei v. H.J. Heinz Co.,* No. 3:15-cv-02961 (S.D. Cal) (ongoing case); *Alaei v. Rockstar Inc.,* Case No. 3:15-cv-02959 (S.D. Cal) (ongoing case). Last year, however, California amended its law so that it's more in line with the federal standards. This change may slow the number of California cases given that the California law had previously been even tougher than the FTC standards and may have caught some companies off guard if they sold products that were truthfully "Made in the USA" – everywhere except California.

FTC Reaches Settlement with Marketers of Pure Green Coffee

When the FTC joined the Department of Justice and a slew of other federal agencies for a press conference on dietary supplements last fall, it announced that it had brought a lawsuit against companies and individuals marketing Pure Green Coffee weight loss supplements. On March 28, 2016, the Florida district court that handled the case approved a settlement between the parties. Under the terms of a stipulated order, the marketers agreed to pay $160,800 in monetary redress and transfer to the FTC assets including net proceeds from selling stocks and a Crown Victoria owned by one of the individuals. Under an avalanche clause in the order, if it is later found that the marketers misrepresented their financial situations, $30,000,000 in monetary redress will become due.

In addition to monetary relief, the order includes injunctive provisions stating the type of evidence the marketers must possess for any future weight loss claims for a food, dietary supplement, or drug. We've asked before how many studies the FTC really expects for weight loss claims, and now as before, the answer seems to be probably more than one. The stipulated order requires "Adequate and Well-Controlled Human Clinical Testing," which is defined as "*human clinical studies* that are randomized, double-blind, and placebo-controlled and that are conducted by [p]ersons qualified by training and experience to conduct such studies." In recent years, orders on other types of cause and effect claims have routinely required "human clinical testing," rather than the plural, "human clinical studies."

FDA DEVELOPMENTS

Identity Crisis Over: Dietary Supplements Can Be "Dietary Supplements"

In its dietary supplement labeling guide, first issued in April 2005, FDA advised that it would not consider the term, "dietary supplement," alone, to be an appropriately descriptive "statement of identity." FDA, however, has reversed course. Revised guidance released in March provides as follows:

> Can the term "dietary supplement" by itself be considered the statement of identity?
> Yes. This term describes the basic nature of a dietary supplement and therefore is an "appropriately descriptive term" that can be used as the product's statement of identity. The statement of identity for a dietary supplement may therefore consist simply of the term "dietary supplement."

The revised guidance also adds that "dietary supplement" may be included as "part of a longer statement of identity (e.g., 'cod liver oil liquid dietary supplement')." The move to allow the use of "dietary supplement," alone, settles a disagreement that has been ongoing between FDA and industry since the passage of DSHEA and the promulgation of a related rule provision on statements of identity for dietary supplements.

FDA Targets Supplements Containing *Acacia rigidula*

Acacia rigidula – also known as *Vachelia rigidula*, Chaparro Prieto, and blackbrush – is an ingredient found in weight loss and bodybuilding supplements. FDA has taken the position that it is a "new dietary ingredient" (NDI), and that there is no evidence that it may be lawfully marketed as such. To sell an NDI, the ingredient must have been present in food, or it must have been the subject of a notification submitted to FDA showing a reasonable expectation of safety. In March, FDA sent warning letters to six companies selling products containing *Acacia rigidula*. The warning letters stated that "[f]ailure to immediately cease distribution of your product . . . and any other products you market that contain *A. rigidula* could result in enforcement action by FDA without further notice."

CPSC DEVELOPMENTS

CPSC Representatives Lay Out Active Agenda

By CHRISTIE GRYMES THOMPSON

At the recent International Consumer Product Health and Safety Organization (ICPHSO) conference in D.C., CPSC representatives raised eyebrows with an

active agenda, which included proposed and recent changes to the civil penalty investigation and corrective action plan status quo. Noted changes included:

- Publication of DOJ Referrals – Chairman Elliot F. Kaye explained that he is exploring procedural avenues that would allow the CPSC to announce when it had referred a civil penalty case to the Department of Justice – a significant departure from the Commission's current practice, as well as that of other government agencies.
- Higher Civil Penalties – Despite industry concerns about the increase in civil penalty amounts over the past year, the Chairman stated that he hopes to seek "double digit" (i.e., at least $10 million) civil penalties when supported by the facts.
- Commission Review of Certain Corrective Action Plans – Commissioners Marietta Robinson and Ann Marie Buerkle discussed the Commission's recent 4-1 vote to require Commission review and approval of corrective action plans for products that were involved in any way in a death. It's unclear, though, exactly how Commission review could expedite the CAP process, or whether the Commission would seek to deviate from the standard notice methods and language.

As these changes and new stances demonstrate, businesses can expect the CPSC to remain active – particularly when pursuing civil penalties – and should make sure that they have a dependable CPSC compliance program in place. Within weeks of the ICPHSO conference, the CPSC announced a record-setting $15.45 million settlement with a company over dehumidifiers it manufactured and imported. This penalty reflects the maximum amount the CPSC can obtain and is over 3.5 times higher than the previous record holder.
For dietary supplements, the CPSC has jurisdiction over child resistant packaging for iron-containing products. Over the last ten years, at least six dietary supplement companies have conducted voluntary recalls in conjunction with CPSC due to allegations that product packaging failed to meet child-resistant closure requirements.

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