CLIENT ALERT

'Tis the Season ... For Supplements

December 2015

For many, the holiday season is a time for indulgence, starting with the banquet of Thanksgiving and continuing through the end of the year. Others look to the future and consider whether to include losing weight and eating healthier as their New Year's resolutions. Some do both—indulge and then atone with promises to do better once January rolls around. The holiday season and the New Year provide major marketing opportunities for manufacturers and retailers of dietary supplements, but those opportunities come with risks that are illustrated by the recent government investigations and consumer class action litigation.

Federal

One week before Thanksgiving, the Department of Justice and federal partner agencies conducted a coordinated, nationwide sweep targeting dietary supplement companies. The announcement was the capstone of a year-long investigation conducted by the Civil Division's Consumer Protection Branch and U.S. Attorney's Offices.

The centerpiece of the year-long initiative was the indictment of six executives and senior officials of USP Labs and S.K. Laboratories Inc., makers of Jack3d and OxyElite Pro. Both products were marketed to weight training and bodybuilding enthusiasts with claims to heighten the effects of exercise and help reduce weight. In reality, however, the products were linked to several severe side effects, including seizures, kidney and liver damage, and at least one death.

The criminal charges against USP Labs included, among others, wire fraud, introduction of misbranded food into interstate commerce with intent to defraud and mislead, introduction of adulterated food into interstate commerce with intent to defraud and mislead, and money laundering. The indictment stated that USP Labs LLC had used the synthetic stimulant DMAA in Jack3d and OxyElite Pro, but represented to retailers and consumers that the supplements contained plant extracts. When the defendants became aware of health risks associated with DMAA, they switched to another synthetic chemical, aegeline. Among other allegations, the government asserted that USP Labs employees obtained false certificates of analysis for DMAA and aegeline from Chinese suppliers, including directing those suppliers to falsely label DMAA as "green coffee" samples in one instance. When the products containing aegeline did not sell well, USP Labs began marketing a version of OxyElitePro that contained cynanchum auriculatum, despite knowledge that the plant could potentially cause liver toxicity. USP Labs instructed its Chinese chemical suppliers to issue false certificates of analysis here as well and described the ingredients as ethanol extract.

In addition to the criminal case against USP Labs, the Federal Trade Commission announced the settlement of two recent enforcement actions against marketers of workout and weight loss supplements. The FTC obtained a judgment of $2.7 million dollars against Classic Productions LLC and its proprietor in the District of Nevada for false and unsubstantiated weight-loss claims regarding its W8-B-Gone product. The $30 million FTC settlement with the NPB Advertising defendants in the District of Florida arose from deceptive marketing claims for green coffee beans.

Recent State Activity

Marketers in the dietary supplement industry have also come under scrutiny from state prosecutors in the past year. In October, the Oregon Attorney General filed a lawsuit against GNC under the state's Unfair Trade Practices Act, alleging that GNC sold two illegal ingredients—picamilon and BMPEA—in dietary supplement products. BMPEA is an amphetamine-like substance used in purported weight-loss products, while picamilon is a synthetic combination of niacin and GABA that purports to increase athletic performance through vasodilation. Neither ingredient is an approved food additive or has been generally recognized as safe (GRAS) in food. The Attorney General asserts that GNC misrepresented that products containing those ingredients were dietary supplements under the Food, Drug, and Cosmetics Act, 21 U.S.C §§ 301 et seq.

Since the initial filing, GNC has been fighting a procedural battle to remove the case to federal court under both federal question and diversity jurisdiction, while also stating that it will seek dismissal of all counts once the venue has been decided. The federal question issue rests on whether the invocation of the FDCA's "dietary ingredient" definition necessarily and exclusively results in the claim arising under federal laws. Oregon has fired back in its filings, arguing that "state law consumer protection claims embedding FDCA standards are now commonplace," and noting that in 1986, the Supreme Court held that "the mere invocation of a standard or definition from the FDCA does not create the kind of 'substantial' federal issue that might, in other circumstances, invite assertion of federal question jurisdiction" (citing *Merrell Dow Pharmaceuticals. Inc. v. Thompson,* 478 U.S. 804 (1986)). A ruling on jurisdiction is expected in late December or early January.

Thousands of miles away, New York Attorney General (NY AG) Eric Schneiderman continued his state's ongoing investigation of the herbal supplement industry (see Crowell & Moring's previous Client Alert here). In September, Schneiderman sent cease and desist letters to 13 manufacturers demanding that they withdraw from the sale, manufacturing, and distribution of adulterated or misbranded "devil's claw" supplements. Though sinister-sounding, devil's claw is an herb native to Africa that has been marketed by the herbal supplement industry for treatment of arthritis and joint pain. Its therapeutic benefits are not generally accepted and the FDA had not approved its usage. According to the NY AG's Office, DNA testing conducted by the New York Botanical Garden had revealed that the manufacturers had substituted a cheaper, related species that contained only some of the same chemicals and was considered "less desirable." The letter recipients included Alternative Remedies Health & Herbs, Biopower Nutrition, Food Science Corp., Vitacost.com, Nature's Sunshine Products, Inc., Nutraceutical International Corp., Olympian Labs Inc., RHG & Company Inc. (dba Vital Nutrients), TUDUVZ, Inc., and The Natural Healing Room & End Time Essentials.

Class Actions

The NY AG's ongoing investigation of herbal supplement has also triggered an avalanche of proposed class-action lawsuits against retailers. An amended complaint in a proposed class-action lawsuit was filed on November 11, 2015, in the District of Illinois against Walgreens Boots Alliance Inc., Target Corp., Walmart Stores Inc. and NBTY Inc, with 20 named plaintiffs hailing from California, Florida, Illinois, Iowa, Ohio, Oregon, Minnesota, Mississippi, Missouri, New Jersey, and New York. The complaint cites the DNA barcode results and alleges that the retailers sold supplements that did not contain the labeled ingredients, such as Ginkgo biloba, Echinacea, and St. John's Wort. The defendants have challenged the efficacy of the testing methods and noted that the lawsuit was filed without reviewing the results of the NY AG's investigation.

The continuing enforcement and private litigation interest in claims used to market dietary supplements counsels for maintaining effective risk management practices, including sound vendor management and supply chain oversight.

Other Articles in This Month's Edition:

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