PUBLICATION

A Gathering Storm in the Dietary Supplement World

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This past February, the New York State Attorney General's office accused four major retailers of selling fraudulent and possibly dangerous herbal supplements and demanded that they remove the products from their shelves. The office's investigation suggested that these retailers – GNC, Target, Walgreens and Wal-Mart – had supplements on their shelves that failed to contain the quantities of the botanical products claimed on their labels. This action was significant because it involved an influential state attorney general, rather than the FDA, initiating an action involving some of the biggest retail and drugstore chains.

While certain supplement manufacturers have questioned the method of testing used by the New York Attorney General's office, all of the retailers have been forced to respond to the highly publicized allegations. Walgreens pulled the products from its shelves nationwide and Wal-Mart vowed to reach out to its supplement providers. To the chagrin of many supplement industry leaders, GNC agreed in early April to undergo additional supplement testing that would be administered by the Attorney General's office.

On April 2, 2015, New York Attorney General Eric Schneiderman was joined by 13 other state attorneys general in sending a letter to Congressional leaders asking for a "comprehensive inquiry" into the supplement industry. These attorneys general pleaded for a more robust oversight role for the FDA and stated that, regardless, "[t]he states will continue to vigorously pursue supplement manufacturers and retailers who break public health and consumer protection laws and endanger the health and well-being of the residents of our states."

Following the lead of the New York Attorney General and adopting many of the same theories, private class action suits were brought in more than a dozen states naming the drug chain and other retailers as well as manufacturers. These suits may be a burden for the defendants because it is probable that insurance defense coverage will be at issue.

On April 22, 2015, the FDA issued Warning Letters to five different dietary supplement manufacturers whose products contained the ingredient BMPEA, an amphetamine isomer. The products were widely promoted for dieters and performance enhancement. In taking this action the FDA was following similar actions taken by Health Canada, but nevertheless took criticism from public interest advocates "for taking so long." A few days later, the FDA issued fifteen more Warning Letters to distributors and manufacturers of dietary supplements containing 1,3 Dimethylbutylamine, otherwise known as DMBA.

Since the beginning of 2015 the FDA has issued more than 30 Warning Letters to dietary supplement manufacturers or distributors. The infractions cited have ranged from failures to observe current Good Manufacturing Practices (cGMPs) to the unlawful inclusion of synthetic steroids in a dietary supplement formula. While many of the Warning Letters addressed labeling and claims that rendered the product to be "intended for use in the cure, mitigation, treatment or prevention" of disease, it is increasingly clear that the FDA will closely scrutinize non-traditional supplements – those with ingredients which are not "a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical or dietary substance." The actions against DMBA also suggest that the FDA will be looking closely at energy drinks.

The combined forces of a more activist group of attorneys general seeking Congressional attention, a receptive class action bar and a Food and Drug Administration determined not to lose its position as pre-eminent champion of consumer protection suggest a coming period of heightened scrutiny in the dietary/herbal supplement industry.

If you have concerns that your company's dietary supplements may be at risk of violating FDA regulations or state consumer protection laws, contact a Baker Donelson attorney in the Firm's FDA Practice Group, and we can assist you with your regulatory compliance program.