Regulatory Oversight of Supplement Industry Continues

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The new administration has hardly hidden its disdain for regulation and disinterest in regulatory oversight. Nonetheless, year-to-date activity by federal regulators signals that agencies have no intention of letting up on their policing of the supplement industry. By mid-July 2017, the U.S. Food and Drug Administration (FDA) had issued nearly the same number of warning letters to supplement companies as it had for all of 2016. The warning letters cite numerous claim, labeling, branding and current good manufacturing practices (CGMP) violations, as discussed more fully below.

Last spring, scores of businesses, including numerous companies in the supplement industry, received letters from the Federal Trade Commission (FTC) calling out their failure to disclose relationships with influencers used to market their products. Recently, the FDA and FTC joined forces to solicit consumers' help in overseeing the supplement industry and asked them to report adverse events, safety concerns, and improper or overstated product claims (see "Dietary supplement concerns? Tell the FTC and FDA," July 25, 2017, FDA Voice). And wherever regulators tread, plaintiff class action lawyers are typically not far behind, as evidenced by the fact that this year, in California alone, more than 45 consumer class actions have been filed against supplement companies. We'll discuss those class actions in a future article. For now, this article focuses on what has attracted the attention of regulators.

Misbranded Products

The FDA continues to crack down on supplement companies that claim their products are intended for use in the cure, mitigation, treatment or prevention of disease (e.g., cure cancer, treat heart problems and promote sexual health). Some of the claims that drew the FDA's attention are not remarkable; others a bit more surprising. Here's a sampling.

Product Claims

As it has done for decades, the FDA has called out companies that claim their products can treat medical conditions, including:

- "Activate numerous anabolic pathways"
- "Increase muscle mass"
- "Explosive muscle & strength gains"
- "Highly anabolic"
- "Blood sugar lowering effects"
- "[Listed ingredients] … have very specific roles to play in … cancer prevention"
- "Reduces brain inflammation"
- "Milk thistle—used as a natural treatment for liver problems … helps repair liver cells damaged by alcohol and other toxic substances"
- "N-acetyl L-cysteine…plays a role in white cell production which may help repair damaged tissue"
- "All natural formula that … attacks obesity"
- "The main focus of the herbs within [supplement product] is blood sugar balancing …"
- "[Supplement product] is an all-natural formula that … attacks obesity …"
- "[Supplement product] with bitter melon is an amazing botanical that acts as a mediator between the body's cell and insulin thereby decreasing resistance to proper insulin function. This unique formula may block excessive formulation of glucose in the blood and enhance tolerance for blood sugars …"
- "There are many well designed studies that have been published in legitimate journals that state garlic has a distinct effect on

the reduction of cholesterol …"

• "Natural relief of pain & irritability from …"

• "Temporarily relieves the symptoms of simple restlessness and wakeful irritability due to ..."

• "Helps reduce gum redness and pain"

Consumer Testimonials

A company that posts testimonials on its website is deemed to have adopted those statements as if they were made by the company itself. Any company that posts a testimonial that touts its products' ability to treat a disease or medical condition is likely to see a warning letter, as evidenced by the following testimonials:

• "Prostate and Bladder Cancer … I was diagnosed with prostate and bladder cancer … I chose to bypass surgery and started my own research to find alternate treatment. In my search, I found an article that explained the effects of [Supplement Product] on cancer cells. I started a daily regiment [sic] of [Supplement Product] about two years ago and low and behold the mass has been steadily shrinking."

• "Arthritis … I used to have arthritic pain in my legs, and since I started using the [Supplement Product], I am now pain free."

• "High Cholesterol and High Blood Pressure … My high cholesterol and high blood pressure ailments are now normal after drinking the [supplement product]."

Scientific Articles

In some cases, website references to academic articles that discuss the medical benefits of particular ingredients found in a company's products has prompted a warning letter. Referring to the ingredients and referencing the article gave rise to the implied claim that the products containing the ingredients could provide the stated medical benefit.

Adulterated Products

Warning letters were issued for adulterated products, including products containing:

• Any herbs or botanicals that are "new dietary ingredients"

• *Acacia rigidula:* "In the absence of a history of use or other evidence of safety establishing that *A. rigidula*, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, [Supplement Product] is adulterated … because it contains a new dietary ingredient (NDI) for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."

cGMP

The FDA continues to cite supplement companies that fail to adhere to cGMP (current good manufacturing practice). The focus is typically on a company's failure to maintain appropriate manufacturing records and perform adequate quality control. Here are examples of some of the circumstances that triggered warning letters:

Manufacturing Records

• Failure to provide sufficient documentation to assure that products received from a supplier for packaging or labeling were adequately identified and consistent with the purchase order

• Failure to maintain product specifications for each supplement manufactured for the purity, strength, and composition of the finished batch

• Failure to maintain a written master manufacturing record (MMR), whether for lack of documentation describing manufacturing processes and product specifications, written instructions for various aspects of the manufacturing process, or corrective action plans for when a product specification is not met

• Written procedures for holding and distributing operations

Quality Control

• Failure to ensure that water that could become a component of a finished batch of dietary supplement complied with applicable federal, state and local requirements

• Failure to reject a component and dietary supplement for which a specification was not met

• Distribution of products that were superpotent for dietary ingredients

• Failure to follow written procedures for laboratory operations, including written procedures for the tests and examinations to determine whether specifications were met

• Failure to follow test procedures

• Failure to collect and properly preserve reserve samples of each production lot

FTC Testimonial Crackdown

In April 2017, the FTC cracked down on companies using social media influencers to tout their products. It issued more than 90 letters to companies that failed to adequately disclose any relationship, including financial, between the influencer and the company. A broad range of industries was caught in the sweep, including supplement companies. The FTC focus on this increasingly prominent marketing tool is a reminder to all that when using influencers to promote products, companies must adhere to the FTC's "Guides Concerning the Use of Endorsements and Testimonials in Advertising."

The foregoing confirms that neither the FDA nor the FTC have any intention of slowing down their regulatory oversight of the supplement industry. And, as we will discuss in a future article, wherever regulators tread, consumer class action lawyers are never too far behind. **NIE**

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