As we all know, discovery in any type of litigation can be long, drawn out, and tedious, and one of plaintiffs' favorite devices is the "corporate representative"

In This Issue
Elizabeth L. Taylor and Lindsey M. Saad provide an overview of the FDA’s recent heightened review of the dietary supplement market.

The Scoop on the FDA’s Updated Approach to the Dietary Supplement Market

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About the Committee
The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the Defense Counsel Journal annually. Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

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If you are like many people, before reaching for your first cup of coffee, you might reach for your multi-vitamin. While most people may pat themselves on the back for adding some extra calcium or glucosamine to their diet, they may be unaware that these dietary supplements are not subject to the same regulations as drugs or devices. The Dietary Supplement Health and Education Act (DSHEA) provided the U.S. Food and Drug Administration (FDA) with authority to regulate dietary supplements in 1994. Since that time, the dietary supplement industry has grown exponentially and is now worth more than $40 billion dollars and is comprised of over 50,000 products. With the supplement market growing rapidly, the FDA has recently taken action to increase the level of oversight for these popular consumables.

First you may ask, what is a dietary supplement? The DSHEA defines the term “dietary supplement” to mean a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the aforementioned ingredients. This definition is key as the FDA’s new focus is on ingredients that do not meet this list of criteria.

The FDA does not have the authority to review dietary supplement products for safety and effectiveness before they are marketed. This means that the seller or manufacturer does not have to prove that the product’s claims are accurate or truthful before the supplement can be sold. Unlike drugs, supplements are not permitted to be marketed for the purpose of treating, diagnosing, preventing, or curing diseases. All responsibility for safety prior to going to market falls upon the manufacturers and distributors of dietary supplements. Only if a supplement contains a new ingredient must the manufacturer notify the FDA prior to marketing the supplement. At this point, the notification is reviewed by the FDA for safety, but not effectiveness.

One of the key safety responsibilities of the FDA is the review of reported serious adverse events by supplement companies and voluntary adverse event reporting by consumers and health care professionals. The FDA also reviews product labels and other product information, such as package inserts, accompanying literature, and Internet promotion of supplements, as resources allow.

With the FDA’s history of a seemingly limited role regarding supplements, you may wonder why the FDA is taking a more active role now. A review of the recent warning letters gives a better perspective of the FDA’s new focus. On February 11, 2019, the FDA posted twelve (12) warning letters and five (5) advisory letters to companies that

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were selling products as dietary supplements that claimed to prevent, treat, or cure Alzheimer’s disease and other serious health conditions. Because the supplements are actually unapproved new drugs or misbranded drugs that have not been proven safe and effective to treat the specific diseases and illnesses advertised, the FDA is focusing its efforts to protect the public from these false claims.

To make the point clear, when the FDA issued the warning and advisory letters in February 2019, the FDA Commissioner, Scott Gottlieb, M.D., also issued a statement, identifying a concern that “changes in the supplement market may have outpaced the evolution of [the FDA’s] own policies and [the FDA’s] capacity to manage emerging risk.”2 The FDA has three priorities when it comes to dietary supplements: to ensure safety, to maintain product integrity, and to foster informed decision-making. With those priorities in mind, the FDA announced in February 2019 several new steps to help achieve its goals of balancing the consumers’ access to supplements while protecting the public from unsafe and unlawful products and, at the same time, holding those accountable who fail to comply with the legal requirements.

The first step involves “communicating to the public as soon as possible when there is a concern about a dietary supplement on the market.”3 In this respect, the FDA is developing “a new rapid-response tool to alert the public so consumers can avoid buying or using products” with an unlawful or potentially dangerous ingredient, and “to notify responsible industry participants to avoid making or selling” supplements with unlawful or dangerous ingredients.4

The second step is focused on ensuring that the FDA’s “regulatory framework is flexible enough to adequately evaluate product safety while promoting innovation.”5 This includes encouraging the submission of new dietary ingredient (NDI) notifications and updating the FCA’s compliance policy regarding NDIs.

The third step is tied to the close work between the FDA and its “partners in the industry to achieve [the] primary goal of protecting public health and safety.”6 In this respect, the FDA created the Botanical Safety Consortium, which is a public-private partnership comprised of individuals from industry, academia, and government who will work together in evaluating not only the safety of botanical ingredients, but also the mixtures in dietary supplements.

The fourth step involves developing new enforcement strategies to ensure the protection of the public health. In this respect, the FDA has made its “internal processes more efficient for taking enforcement action when products claiming

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3 Id.
4 Id.
5 Id.
6 Id.
to be supplements contain unlawful ingredients, including drug ingredients.”

The fifth and final step centers on public dialogue and engaging the public to gain feedback from dietary supplement stakeholders. This includes looking into whether DSHEA and its existing laws should be modernized.

In addition to the above steps, the FDA also reestablished the Dietary Supplement Working Group, which is made up of representatives from several centers and offices across the FDA. The Dietary Supplement Working Group has been tasked with identifying opportunities to modernize the FDA’s oversight of dietary supplements by a review of its organizational structures, processes, procedures, and practices currently in place.

Although the changes to the FDA regulatory framework are not necessarily new or surprising, the agency has made it clear that it will be focusing on enforcement and modernization of the rules and regulations when it comes to dietary supplements. We can expect that dietary supplement companies may face a closer review of labeling, dietary ingredients, and the purported benefits of the supplements. As attorneys, we can advise our clients to stay ahead of this regulatory review by proactively taking steps to make sure that their products are in compliance. The next time you pop your multi-vitamin, think about how you can work with your dietary supplement clients to avoid being the target of the next warning letter or class action.

7 Id.
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