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Bringing Dietary Supplements to Market: Key Requirements and Best Practices

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The dietary supplement market is a growing industry. According to data from the National Center for Health Statistics, dietary supplement use by Americans has jumped for all age groups compared with the last study a decade earlier (2007–2008 to 2017–2018). In 2020, the global dietary supplements market was estimated at $140.36 billion. The market is expected to grow by over another $11 billion in 2021.

What Is a Dietary Supplement?

As defined in Section 321 of the Federal Food, Drug, and Cosmetic Act (FDCA), a "dietary supplement" is:

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following **dietary ingredients**:
>
> > (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

In contrast to products regulated as drugs, a dietary supplement may not be used to treat, diagnose, prevent, or cure diseases.

There are other statutory requirements for dietary supplements. For instance, they must be in "tablet, capsule, powder, softgel, gelcap, or liquid form," and "not be represented as a conventional food … for use as a sole item of a meal or of the diet." That last requirement is key when determining whether a particular product would be regulated by the FDA as a dietary supplement or a conventional food: whether a product is classified as a dietary supplement or a conventional food will depend on how it is represented. Determining the appropriate regulatory product category for your product at the outset is critical in understanding its pathway to market.

Pathway to Market: New Dietary Ingredient and Old Dietary Ingredient

Because dietary ingredients are explicitly excluded from the statutory food additive definition, they may not be brought to market under the same pathways as food additives.

There are several dietary ingredient-specific pathways to market. A dietary ingredient can fall into one of two categories: (1) a new dietary ingredient (NDI) – a dietary ingredient that was not marketed in the United States before October 15, 1994; or (2) a dietary ingredient that was already on the market in the United States before October 15, 1994 (often referred to as an "old dietary ingredient" (ODI) or "grandfathered" dietary ingredient). Premarket approval by the FDA is not required for an ODI.

Under the NDI pathway, there are two ways to bring a dietary supplement to market. A company can introduce a dietary supplement with an NDI by filing a new dietary ingredient notification (NDIN). This process is for dietary ingredients entirely new to the food supply. Alternatively, a company can demonstrate that the dietary ingredient has already been present in the food supply and is safe for consumption at the levels contemplated, avoiding the lengthy NDIN process.

How May an NDI Be Introduced for Inclusion in a Dietary Supplement Through the NDIN Process?

Companies planning to introduce an NDI through an NDIN must notify the FDA at least 75 days before introducing the product into interstate commerce. The NDIN must provide evidence to demonstrate the NDI's safety. Among other things, information required in an NDIN includes the name of the NDI, the level of the dietary ingredient in the dietary supplement, the conditions of use indicated for the supplement, and evidence of safety. The standard for safety is "reasonably expected to be safe." A successful NDIN will result in a no-questions letter.

How May an NDI Already Present in the Food Supply Be Authorized for Inclusion in a Dietary Supplement?

An NDI may be used in a dietary supplement without an NDIN only if it is already present in the food supply as an article used for food and in a form in which the food has not been chemically altered. NDIs that meet these requirements may be marketed as dietary ingredients without notifying the FDA.

It is not enough that the dietary ingredient be generally recognized as safe (GRAS) or has been approved through a food additive petition (FAP). The NDI must have been introduced into the food supply.

The FDA has viewed "chemical alteration" broadly. For instance, the FDA considers the following activities to result in chemical alteration: making or breaking a chemical bond (unless reversed in water or during digestion), distillation, chromatography, filtration, the use of solvents other than water or aqueous ethanol, and changes in fermentation conditions.

The GRAS procedure does not apply to dietary ingredients because they are excluded from the definition of food additives. That said, a GRAS conclusion may still be reached for a substance for non-dietary ingredient use. Once the substance is included in the food supply, the substance can be used as a dietary ingredient.

What if a Supplement Includes a Grandfathered Dietary Ingredient?

An ODI is a dietary ingredient that was marketed in the United States before October 15, 1994. While there are no official lists published by the FDA, several trade associations have prepared lists of ODIs that can help direct a manufacturer to potential ODIs. The substance to be used as an ODI must not have had a change to its identity relative to the product marketed before October 15, 1994. The FDA defines "identity" to encompass, among other things, physicochemical structure or properties, purity and impurities, bioavailability or toxicity, consideration of the source material, and nano-sized particles. If an ODI is marketed for use as a dietary supplement without a change in identity, then no submission to the FDA is needed before use in a dietary supplement.

Common Pitfalls in Marketing Dietary Supplements

When developing products, manufacturers of dietary supplements should consider the following pitfalls to mitigate regulatory enforcement and litigation risk:

Marketing dietary supplements without an appropriate U.S. regulatory status

The FDA has issued warning letters for dietary supplements that are not present in the food supply and for which the manufacturer has failed to submit an NDIN despite the dietary ingredient being an NDI. In those cases, failure to submit an NDIN renders the dietary supplement adulterated under the FDCA. A product's failure to have an appropriate U.S. regulatory status has also been used by plaintiffs' attorneys to allege consumer deception. In light of the regulatory enforcement and litigation risk, manufacturers should work closely with formulators and copackers to ensure all ingredients used in finished dietary supplements have an appropriate U.S. regulatory status.

Safety concerns

Although consideration of a history of use or other evidence of safety is incorporated into the NDIN process, the FDA has issued warning letters over specific safety concerns over other non-FDA scrutinized substances, like kratom, in dietary supplements. To mitigate safety concerns, manufacturers should also ensure that their products are manufactured in compliance with current good manufacturing practices and that they keep tight controls over contract manufacturers.

Making disease or other claims often scrutinized

Finally, disease claims are one of the most common types of advertising claims that the FDA challenges for dietary supplements. Explicit and implicit marketing claims that a product is intended for use in the cure, mitigation, treatment, or prevention of disease would classify the product as a drug under the FDCA and would require premarket approval.

Additionally, there are mechanisms in place to utilize marketing claims for dietary supplements. These include the ability to make claims about the impact on the structure or function of the body, authorized health claims, or qualified health claims. Such claims require adequate scientific substantiation ("significant scientific agreement" in the case of authorized claims) and may also require a disclaimer on the package.

Beyond disease claims, dietary supplement manufacturers should be aware of other claims targeted by consumer class action attorneys, including "natural" claims, claims that a product contains a certain level of marketed ingredients, and product effectiveness claims. Marketing and legal teams should work together to ensure compliant labeling and the development of claims that minimize risk of challenge.

Conclusion

As the use of dietary supplements continues to grow, regulated industry should be prepared for increased scrutiny from the FDA, competitors, and consumers over dietary supplements and related marketing practices.

The team at Alston & Bird will continue to provide dietary supplement regulatory analysis to advise clients on the business and legal implications of coming to market or expanding their footprint in the dietary supplement industry.

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