

Adaptogens and FDA/FTC Compliance

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Adaptogens ingredients refer to supplements and herbs that are used in the practice of alternative medicine. The makers and sellers of products with adaptogen ingredients claim that the ingredients have properties that help to strengthen and normalize a person's bodily functions. According to [Michigan State University](#), adaptogenic ingredients can be found in *"traditional Ayurveda and Chinese medicine and other holistic herbal alternative medicine practices."*

According to the [European Medicines Agency](#), adaptogen ingredients must include:

- An almost non-toxic response in the recipient.
- Non-specific pharmacological properties that increase an organism's resistance to a broad spectrum of adverse biological, chemical, and physical factors.
- The ability to be a regulator by having a normalizing effect on an organism's various organ systems or other profound pathologic changes in the organism.

[According to the Washington Post](#), consuming adaptogenic drinks in moderation has a low risk. Still, consumers need reliable advertising and marketing claims. The Post article states that adaptogens are a *"broad class of herbs, botanicals, and mushrooms that have been associated with enticing effects — including relieving stress and improving mood — that are sometimes linked to the experience of drinking alcohol."* Adaptogens are being marketed as an alternative to alcohol. Nonalcoholic beverages promise some of the same reduced stress effects as alcohol drinks. Some nonalcoholic beverages from companies such as Kin Euphorics, Curious Elixirs, and Rasasvada include adaptogens.

There isn't any current research or scientific evidence that currently supports the efficacy of adaptogen ingredients. The ingredients do not qualify as drugs, according to the FDA definition of drugs because they do not *"treat, cure, or prevent any known ailments or diseases."* FDA does review any claims by a manufacturer or seller that the adaptogen ingredients act as drugs. If a company markets products as drugs, the company will likely be sent a warning letter to cease any such claims on the grounds that the products are adulterated and misbranded.

Adaptogens are considered dietary supplements. FDA has oversight over dietary supplements and dietary ingredients. Generally, FDA is limited in its ability to regulate supplements, according to Michigan State University, before the supplements are available for sale. While the manufacturers are responsible for the ingredients, FDA generally cannot recall the supplements until a sale has taken place and a consumer has filed a complaint.

IS YOUR PRODUCT A DIETARY SUPPLEMENT OR AN FDA-REGULATED DRUG? (PART 2)

In today's video, we'll talk about some more not so obvious ways that FDA can classify your dietary supplement as a drug.

What ingredients are common in adaptogens?

According to MSU, some common adaptogen ingredients include *"Ashwagandha, Astragalus root, Bacopa Monnieri, cordyceps, Eleuthera, holy basil, licorice, maca, maitake, Rhodiola rosea (Arctic root), reishi, schizandra, shiitake, Siberian ginseng, and wild yam."*

Common adaptogen claims

Some of the statements that nonalcoholic drink companies make are:

- Kin Euphorics website says *"BYE BYE BOOZE. HELLO COSMIC WONDER,"* and advertises that its drinks have *"mood-boosting"* or *"mind-calming"* ingredients.
- Curious Elixirs describes its offerings as *"complex booze-free cocktails infused with adaptogens to help you unwind."*

Adam Perlman, a physician and integrative and functional medicine specialist at the Mayo Clinic says that. *"Very often there is some science to back these claims, but the science is often not as definitive as we'd like it to be."*

Mikhail Kogan, a geriatrician and medical director of the Center for Integrative Medicine at George Washington University says that adaptogens refers to a natural substance that *"somehow protects against negative impacts of stress."* *"Kogan said he uses tinctures of adaptogens himself, including schisandra, ginseng and rhodiola, and has recommended them to patients."*

Norbert Kaminski, a professor of pharmacology and toxicology and director of the Center for Research on Ingredient Safety at Michigan State University says, *"The idea is these adaptogens help maintain your body and equilibrium."*

While the functions associated with the ingredients largely match the advertising language for nonalcoholic adaptogenic drinks, the claims are often vague. Kaminski said. *"The things that they supposedly do often are very difficult to measure. You can't quantify a lot of this."*

Adaptogenic products such as herbs, plants, and mushrooms do have a history of healing abilities – *"But while some scientific evidence suggests there are benefits to consuming adaptogens, experts said much of the research involved animal studies, and that the few human trials were limited by small sample sizes."*

Do adaptogens actually meet the claims that these products reduce stress and balance systems? Adaptogen warning letters.

The FTC also has oversight over false claims makers and sellers of adaptogen ingredients make. The FTC regulates how a manufacturer or sell can advertise and market its dietary supplements. Claims must be truthful and substantiated. Claims cannot be misleading. FTC can send warning letters to the manufacturers and retailers of the dietary supplements if the agency believes the supplements are harmful or if the claim about their efficacy is improper.

For example, claims that adaptogen ingredients can cure, prevent, or mitigate COVID-19 symptoms will be met with FDA and FTC warning letters.

benjaminmcevoy.com – 607149 – 05/14/2020 | FDA.

FDA and FTC filed a joint warning letter against Benjamincovey.com claiming that the respondent sold products, including dietary supplements, through Amazon and promoted the products on the company website. The website includes claims *"representing or implying that the products can mitigate, prevent, treat, diagnose, or cure COVID-19[2] in people."*

The warning letter asserted that these claims cause the products to be classified as unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). The warning letters also stated that the products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. Further, the warning letters said that the introduction or delivery of these products into interstate commerce violated the FD&C Act and that it was illegal under the FD&C Act *“to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.”*

Some of the claims that the warning letter said were improper included:

*“Ashwaghandha [Amazon associate link] . . . **Ashwaghandha is an adaptogen . . . which has many studied but yet to be understood positive effects on the immune system. Adaptogens reduce cortisol levels and improve immune response** . . . You can learn more and buy ashwaghandha here [Amazon associate link].”*

The respondent was given a deadline to respond to the warning letter or face further action.

A warning letter was filed against Red Moon Herbs.

The warning letter was filed by FDA and the FTC. The letter stated that agencies reviewed the company’s website and social media accounts. The agencies found that the company sold numerous products that *“are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.”* The warnings made similar assertions to the previous warning letter (Benjamincovey.com) that the products are new drugs and are thus adulterated, misbranded, and violate various provisions of the FD&C Act.

Included among the postings was the statement:

*“Immunomodulating herbs – my top go-tos which are showing up again and again in the building literature surrounding this pandemic are astragalus, any and all medicinal mushrooms (reishi, turkey tail, chaga, lion’s mane, and Mushroom Elixir are favorites), and **adaptogens** including ashwagandha and ginseng. Echinacea and usnea are both effective immune stimulants and usnea have an affinity for the lungs which may prove relevant here. Astragalus and reishi are particularly gentle and good for all ages and my three year old takes them daily.”*

The respondent was also given a deadline to reply or face further legal action.

Claims about adaptogen products

FDA and dietary supplements

FDA regulates finished dietary supplement products and dietary ingredients. The FDA regulates dietary supplements differently than drugs or food.

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that the products meet all the requirements of DSHEA and FDA regulations.

FDA has the authority to take action (usually beginning with warning letters) *“against any adulterated or misbranded dietary supplement product after it reaches the market.”*

According to the FDA, “FDA’s Center for Food Safety and Applied Nutrition (CFSAN) is responsible for the agency’s oversight of these products. The Dietary Supplement Health and Education Act (DSHEA) of 1994, which amended the Federal Food, Drug, and Cosmetic Act, created a new regulatory framework for the safety and labeling of dietary supplements. **FDA is not authorized to review dietary supplement products for safety and effectiveness before they are marketed.**”

FDA and new dietary supplement regulation

According to former FDA Commissioner Scott Gottlieb, M.D., ¾ths of Americans take a dietary supplement on a regular basis. 4/5ths of seniors take a dietary supplement. Based on those large numbers, FDA announced new goals for dietary supplement regulation. Since the Dietary Supplement Health and Education Act (DSHEA) was passed more than 25 years ago, the dietary supplement industry has grown from \$4 billion to \$40 billion and from about 4,000 products to at least 50,000 products. While most manufacturers and sellers are responsible, the number of companies “marketing potentially dangerous products or making unproven or misleading claims about the health benefits they may deliver” has increased.

These proposed new goals apply to all dietary supplements including adaptogens.

Commissioner Gottlieb stated for the FDA:

- The first priority is ensuring safety – that the products don’t cause harm.
- The second priority is “product integrity: we want to ensure that dietary supplements contain the ingredients that they’re labeled to contain, and nothing else, and that those products are consistently manufactured according to quality standards.”
- The third priority is “informed decision-making. We want to foster an environment where consumers and health care professionals are able to make informed decisions before recommending, purchasing or using dietary supplements.”

This last priority gets to another reason why it’s important to speak with an experienced healthcare lawyer. Skilled healthcare lawyers advise both the manufacturers and sellers of dietary supplements such as adaptogens and the physicians who recommend these supplements about their FDA compliance requirements.

The key steps Commissioner Gottlieb announced (that logically apply to adaptogens) are:

- Better communication when there are concerns an ingredient is illegal, potentially dangerous, and shouldn’t be marketed as dietary supplements – including faster notifications about a product’s concerns to the public.
- Flexibility in evaluating product safety while promoting innovation -including “steps to foster the submission of new dietary ingredient (NDI) notifications.”
- “Working closely with our partners in industry to achieve our primary goal of protecting public health and safety. As the dietary supplement industry develops new products and ingredients, advances new delivery systems and innovates in other ways, the FDA must do more to leverage its existing resources and authorities to evaluate these products.” One step is the creation of the Botanical Safety Consortium, “a public-private partnership that will gather leading scientific minds from industry, academia and government to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements.”
- Developing new enforcement strategies including sending warning letters, and continuing compliance and “enforcement efforts against firms that have shown persistent inability to comply with the current good manufacturing practice requirements for dietary supplements, and taking action to protect the public against unsafe imports and recalled products.”

Many companies are making and selling products with herbs and other adaptogens that claim to relieve stress. These companies and any doctors who recommend adaptogens to their patients need to understand the FDA regulations that regulate drugs and dietary supplements. Skilled healthcare lawyers help clients take proactive steps to reduce the risk of FDA or FTC complaints and responsive steps if a company or doctor receives an FDA or FTC warning letter.

Makers of dietary supplements and the physicians who recommend or prescribe them should contact Cohen Healthcare Law

Group, PC to discuss FDA compliance and other regulatory issues. Our [experienced healthcare attorneys](#) help physicians and health companies understand their compliance requirements.

[Contact](#) our [healthcare law](#) and [FDA attorneys](#) for legal advice relevant to your healthcare venture.