

Red Flags that Leads to FDA Warning Letters

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The FDA regulates dietary supplements, cosmetics, medical devices, and many other products. It's essential to consult with an experienced FDA warning lawyer before developing and marketing these products. Establishing proper compliance protocols and understanding the common violations the FDA looks for as early as possible can help minimize the odds of a warning letter.

The FDA doesn't give companies or individuals much time to reply to a warning letter. The consequences for failure to comply can be extremely expensive. There are usually substantial fines. In some cases, the FDA may order that development and distribution cease. FDA or other agencies might even file criminal complaints.

HOW TO RESPOND TO AN FDA WARNING LETTER ABOUT DIETARY SUPPLEMENTS OR COSMETICS

The United States Food and Drug Administration (FDA) regulates much more than food and drugs. It regulates dietary supplements, cosmetics, medical devices, tobacco products, animal food, [...]

Dietary supplements

The FDA regulates both dietary supplements and dietary ingredients. Unlike other foods and drugs, dietary supplements are regulated pursuant to the Dietary Supplement Health and Education Act of 1994 (DHSEA). The DHSEA precludes manufacturers and distributors of the dietary products from marketing products that are misbranded or adulterated. Makers and distributors of dietary supplements and ingredients have a duty to study the safety of the products and how they're labeled to make sure they comply with FDA and DHSEA regulations. The FDA will pursue companies and individuals if these adulterated or misbranded products reach the market.

The Food, Drug, and Cosmetic Act defines a dietary supplement as:

"A vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances."

A major red flag for drug supplement companies is that they should NOT qualify as drugs. This means that supplements shouldn't make claims that they can treat, diagnose, prevent, or cure diseases. Statements such as "this product reduces pain" or "treats cancer," are likely to result in an FDA warning letter.

FDA ISSUES WARNING LETTER TO DIETARY SUPPLEMENT COMPANY FOR INCLUDING CANCER OR DIABETES IN SEARCH FIELD

The FDA issued a warning letter citing a dietary supplement company for its online content. In its warning letter to dietary supplement manufacturer M.D.R. Fitness Corp., the FDA warned that [...]

Examples of FDA warning letters for dietary supplements

Adulterated dietary supplement – Avalon Packaging

On November 8, 2018, the FDA issued a warning letter to Avalon Packaging, a Utah company. The FDA inspected the company's facility and collected samples containing kratom. The FDA warning letter asserted the following violations:

Adulterated dietary supplement. The samples were found to be adulterated because they contained 13 strains of the human pathogen *Salmonella*. Healthy people who contract salmonella can develop severe diarrhea, fever, chills, abdominal pain, and other complications. For less healthy individuals, salmonella can be fatal. The FDA warning letter identified the 13 strains.

CGMP violations. The FDA also found that the company violated Current Good Manufacturing Practices (CGMP). The FDA asserted that it was the violation of these safety practices that allowed the dietary supplements to become adulterated. The warning letter further indicated that the company was made aware of its defective practices and had failed to properly establish and follow written safety procedures. The letter added:

“... failed to establish specifications for any points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.70(a).”

The FDA warning letter said that it reviewed the company's response to early letters but that the company had not properly detailed its corrective actions. The FDA said that Avalon Packaging had failed to

“prepare and follow a written master manufacturing record (MMR) for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch as required by 21 CFR 111.205(a).”

New Dietary Ingredient. The warning letter also addressed the dietary ingredient “kratom”. The letter cited the relevant law in stating that a dietary supplement that has a dietary ingredient that wasn't marketed in the US before October 1, 1994 is adulterated unless:

1. The dietary supplement with the new ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered or
2. There is proper evidence of its safety

The FDA found that the company has yet to show its supplement, with “kratom”, meets either of these requirements.

The FDA warning letter gives the dietary supplement maker (name the company) 15 days to identify what corrective steps will be taken.

Misbranding – Dietary supplement is a drug – DynaPro International

On October 31, 2018, the FDA issued a warning letter to a co-owner of DynaPro International, Inc. located in Utah. The FDA warning letters stated that the agency found violations after inspecting the company facility, reviewed the product labels, and reviewed the company website. The FDA found that:

“The company labels and website establish that one company product is a drug because it is ‘intended for use in the cure, mitigation, treatment, or prevention of disease.’”

The product is misbranded because there are improper claims that the product can help people with ulcers and diabetes. The FDA found that the product is not safe and should be qualified as “new drugs” which need to be verified based on scientific data. The drug is also misbranded because it doesn’t have “adequate directions for intended use.”

The warning letter also found that the dietary supplement products were adulterated because they didn’t meet Current Good Manufacturing Practice.

The FDA further found that the dietary supplements (with names such as DynaPro Vanilla Supreme, DynaPro Stress Remeday, and DynaPro Berry Supreme) are misbranded because:

- The products doesn’t declare the necessary nutrition information
- Doesn’t declare the quantity of certain ingredients
- Improperly list dietary ingredients that aren’t present or have zero amounts
- Doesn’t properly state that they are dietary supplements
- Other violations

Further, one product that was listed as a dietary supplement was also labeled *“Use it as a snack or a full meal replacement.”* Dietary supplements can’t be labeled as both a dietary supplement and a conventional food.

10 LEGAL TIPS TO STOP FDA FROM CLASSIFYING YOUR DIETARY SUPPLEMENT AS A DRUG

Your dietary supplement products could be regulated as a new drug by FDA, unless you pay attention to these regulatory fundamentals.

Misbranding – Dietary Supplement as Drug – Teeter Creek Herbs, Inc.

On May 21, 2013, the FDA issued a warning letter to the owners of Teeter Creek Herbs, Inc. The letter was issued base on an investigation of their Missouri facility.

CGMP violations. The facility inspected noted significant violations of the Current Good Manufacturing Practice regulations for dietary supplements. Some of the CGMP violations included claims that the dietary supplement manufacturer:

“Failed to qualify a supplier of a component by establishing the reliability of the supplier’s certificate of analysis (COA) through confirmation of the results of the supplier’s tests or examinations, as required by 21 CFR 111.75(a)(2)(ii)(A). “

“Failed to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.70(a).”

“Failed to prepare a written master manufacturing record (MMR) for each unique formulation of dietary supplement that you

manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch, as required by 21 CFR 111.205(a).

“Failed to include the strength, concentration, and weight of the dietary supplement to be manufactured, and the measure of each dietary ingredient for each batch size [21 CFR 111.210(a)]. “

Unapproved New Drug. The FDA also reviewed samples of the labels for the dietary supplements (with names such as Lymphaid, Sheep Sorrell, and Blood Build). The review indicated that the products are drugs because they are “intended for use in the cure, mitigation, treatment, or prevention of disease”

Some of the claims that indicate the dietary supplements are drugs included:

- Featured Herb: Astragalus [an ingredient in your Immunaid and Astragalus products]:
 - *“They should be considered for those with cancer, those who have had long-term infections like Hepatitis, as well as by those with auto-immune and allergic ... disorders ... The herbs include Astragalus, Maitake, Shiitake, Reishi and Turkey Tail mushrooms, Elecampane, and Ginseng.”*
 - *“Astragalus is ... for those with chronic immune deficiencies leading to re-current infections; including viral infections.”*
 - *“It is also a valuable aid in recovery from infectious diseases.”*
 - *“Astragalus and the mushrooms ... valuable for those with any form of chronic Hepatitis or ... for those who have been taking chemo or other drug therapy.”*
- Featured Herb: Dandelion [an ingredient in your Blood Build product]:
 - *“The leaves have ... relieve high blood pressure.”*
 - *“It is an aid in...hepatitis, gall bladder...formation of stones...”*
 - *“[A]n aid in food allergies.”*
 - *“A preventative in high cholesterol and arteriosclerosis.”*
 - *“Dandelion ... A blood purifier for the toxins that aggravate arthritis, rheumatism and gout.”*
 - *“Used ... for chronic metabolic disorders; ... cirrhosis, both high and low blood sugar, anemia.”*
 - *“[O]ther uses ... for Dandelion include breast conditions (mastitis, breast tumors and cancer) ...”*

The FDA found that the above products:

“The products identified above are not generally recognized as safe and effective for the above referenced uses and therefore, the products are “new drugs” under section 201(p)(1) of the Act [21 U.S.C. §321(p)(1)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C §355(a)]. FDA approves a new drug because of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.”

The FDA also found that since these products aren’t amenable to self-diagnosis and treatment by non-medical practitioners – that adequate directions couldn’t be written. The lack of adequate directions means the products are misbranded.

Labeling violations. The FDA further stated that even if the dietary supplements didn’t have disease claims, they would still be misbranded because the labeling requirements of the Code of Federal Regulations (CFR part 201) were not met. These violations included failing to list quantities of the ingredients, failing to include a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with such dietary supplement, and other

failures.

The FDA has the authority to issue warning letters for violations of their regulations and violations of many federal laws including the Dietary Supplement Health and Education Act of 1994 (DHSEA) and the Food, Drug, and Cosmetic Act. Some of the products the FDA regulates include dietary supplements, cosmetics, and medical devices.

Dietary supplement manufacturers and distributors need to understand that the FDA will examine their facility, their products, their labels, their websites, and their marketing. The FDA will almost certainly look for claims that the dietary supplements can be used to diagnose, treat, and cure diseases. The FDA also regularly reviews labels. Common violations include new drug violations, adulteration, misbranding, and failure to follow current good manufacturing processes.

If the recipient of the FDA warning letter fails to properly comply with the terms of the letter, the company could face civil and criminal penalties, the seizure of their assets, and an injunction to cease making and distributing their products.

FDA warning letters are published online. The best legal protection is legal prevention—i.e., the best remedy is to establish procedures that minimize the likelihood a warning letter will be issued. If FDA has issued a warning letter with respect to your dietary supplement or cosmetics product, you need to properly respond to the warning letter.

Experienced FDA lawyers understand why FDA dietary supplement, cosmetic, or other warning letters are issued. FDA attorneys help companies review their claims and labeling, and respond to the FDA warning letter.

Contact our FDA warning letter lawyers at Cohen Healthcare Law Group, PC for legal advice regarding your FDA warning letter.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.