



United States Regulatory Disclosure

Classification

Aviara's products are classified as dietary supplements by the U.S. Food and Drug Administration (FDA). According to the **Dietary Supplement Health and Education Act of 1994 (DSHEA)**, a dietary supplement, also known as food supplement or nutritional supplement, is a preparation intended to supplement the diet and provide nutrients, such as vitamins, minerals, fiber, fatty acids, or amino acids, that may be missing or may not be consumed in sufficient quantities in a person's diet.

Regulation

The FDA regulates dietary supplements as a category of foods, and not as drugs. While pharmaceutical companies are required to obtain FDA approval which involves assessing the risks and benefits prior to their entry into the market, dietary supplements do not need to be pre-approved by the FDA before they can enter the market. (As long as it can be shown that the ingredients were marketed to the public before October 15, 1994.- which all of the ingredients in Aviara's products were)

On September 24, 2007, the FDA implemented a "**current Good Manufacturing Practices**" (cGMP) policy to ensure dietary supplements "are produced in a quality manner, do not contain contaminants or impurities, and are accurately labeled". The cGMP's policies cover the manufacturing, packaging, labeling and storing of supplements, with requirements for quality control, design and construction of manufacturing plants, testing of ingredients and final products, record keeping and complaint processes.

Mandatory Disclosure

When a manufacturer makes a structure/function health claim related to its products, it is required to publish a statement or "disclaimer" which is required by law (DSHEA). In general, these claims describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; and that they are not approved by FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.

We publish scientific and academic research reports on our website that link the ingredients in our products to potential health benefits. The studies that we provide are provided as a service to the public. They are not intended to make express or implied health or disease claims, as Aviara's products are food, not drugs. The reports do not constitute labeling or advertising for any Aviara product. Instead they are intended solely for educational and informational purposes.

There are various sections of the Aviara website that make structural or functional health claims. **These statements have not been evaluated by the Food and Drug Administration. Our products are not intended to diagnose, treat, cure, or prevent any disease.**

