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SUMMARY OF FDA & FTC REGULATIONS

The U.S. Food and Drug Administration ("FDA") is empowered to investigate unsubstantiated and/or false claims made for products for sale in or into the U.S. that are intended to diagnose, mitigate, prevent, treat, or cure. The Food, Drug, and Cosmetic Act (the "FDCA") and the Fair Packaging and Labeling Act (the "FPLA") regulate the manufacture, marketing, and sale of food, drugs, and cosmetics. The FDCA and FPLA applies to labeling of products, misbranding of products, and adulteration of products, and applies equally to manufacturers, packers, distributors, and retailers, who are responsible for assuring that the products are not adulterated or misbranded. The laws also apply to components and packaging as well as to finished products.

The U.S. Federal Trade Commission ("FTC") has jurisdiction over companies that advertise or market products to the general public by using the Internet, radio, television, newspapers, and magazines. The Federal Trade Commission Act (the "FTCA") allows the FTC to act in the interest of all consumers to prevent deceptive and unfair acts or practices. The FTCA prohibits unfair or deceptive advertising in any medium. That is, advertising must tell the truth and not mislead consumers In addition, claims must be substantiated, especially when they concern health, safety, or performance. The type of evidence may depend on the product, the claims, and what experts believe necessary. Sellers are responsible for claims they make about their products and services. Third parties, such as advertising agencies or website designers and catalog marketers, may be liable for making or disseminating deceptive representations.

The FTC and FDA work together under a long-standing liaison agreement governing the division of responsibilities between the two agencies. The dietary supplement industry is especially monitored because it affects the public health and safety. Scientific research on the associations between supplements and health is accumulating rapidly, so the role of the FDA and the FTC is to ensure that consumers get accurate information about dietary supplements so that they can make informed decisions about these products. As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media. Because of their shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible.

Advertising agencies or website designers are responsible for reviewing the information used to substantiate ad claims. They may not simply rely on an advertiser's assurance that the claims are substantiated. In determining whether an ad agency should be held liable, the FTC looks at the extent of the agency's participation in the preparation of the challenged ad, and whether the agency knew or should have known that the ad included false or deceptive claims.

- The FDA has a mandate to pursue civil charges and impose fines and obtain court injunctions, and may refer any matter to the FDA Office of Criminal Investigations which may pursue criminal charges which may lead to imprisonment and fines if it finds criminal conduct.
- The FTC may pursue civil or criminal charges which may lead to the imposition of fines and court injunctions against companies that violate the law.