TOGETHER, BUILDING PEOPLE®

U.S. Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) is responsible for protecting and promoting public health, which includes control and supervision of the dietary supplement industry. In 1994, the U.S. Congress created the Dietary Supplement category by enacting the Dietary Supplement Health and Education Act of 1994 (DSHEA), which amended the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements.

Dietary Supplement Health and Education Act

DSHEA mandates that dietary supplements are "not intended to diagnose, treat, cure, or prevent any disease." Therefore, manufacturers and marketers of dietary supplements cannot say that their products diagnose, treat, cure, or prevent diseases, but they can make structure/function claims, so long as there is competent and reliable scientific evidence to support those claims.

What is a structure/function claim? A structure/function claim describes the role of a nutrient or dietary ingredient intended to affect or maintain normal structure or function of the human body. Think about supporting health and not treating disease. Please refer to Product Claims Policy and Approved Product Claims for more discussion on structure/function claims.

What is a disease? A disease is a disordered or incorrectly functioning organ, part, structure, or system of the body resulting from genetic or developmental errors, infections, poisons, nutritional deficiency or imbalance, toxicity, or unfavorable environmental factors.

What is a disease claim? A disease claim is any statement about a product that contains a word or image that references any disease.

Why can't we make disease claims?

- Our products are not drugs. Drug manufacturers must go through a rigorous and tedious process to obtain approval from the FDA, which includes discovery and development, preclinical research, clinical research, FDA review, and FDA post-market safety monitoring. It usually takes about ten years for a drug to be developed and approved for prescription.
- In accordance with DSHEA, it is illegal to make disease claims in connection with any dietary supplement. While dietary supplement products do not go through a formal FDA review process for approval of claims, the company is required to submit to the FDA a list of claims that it intends to make about each individual product. The claims 4Life® lists are based upon competent and reliable scientific evidence relating to individual ingredients that are on the same level within a serving of the dietary supplement. Every 4Life product has a different ingredient profile, so the claims for each product vary. The list of claims compiled for each product represents the entirety of claims which can be made by the company and you as a distributor. Claims that relate to each specific product can be found in specific Product Profile Sheets on 4life.com.
- Making disease claims in connection with dietary supplements is not safe. Dietary supplement products are not tested for safety and efficacy in disease patients.
- Making disease claims in connection with dietary supplements is misleading to consumers. Consumers might be tempted to substitute their prescription medications (which have gone through the FDA's stringent approval process for safety) with dietary supplement products (which have not gone through the FDA's stringent approval process for safety).

What about special populations?

- Safety and efficacy of dietary supplement products have not been evaluated in pregnant and nursing women. Consumers should consult with their physician prior to use.
- Safety of dietary supplements products have not been evaluated in children. 4Life currently has three products for children—RiteStart® Kids & Teens, 4Life Transfer Factor® Chewable Tri-Factor® Formula, and 4Life Transfer Factor® RioVida® Tri-Factor® Formula. Consumers should consult with their physician prior to use.
- People with auto-immune issues should consult with their physician prior to use.
- People who have had organ transplants should consult with their physician prior to use.

DSHEA applies to all dietary supplement manufacturers and marketers (including 4Life and you as a distributor), encompassing all labeling (product labels and any other marketing collateral in print, on websites, etc.) and marketing (including written presentations, oral presentations, video presentations, meetings, websites, social media venues, and books). No one, including physicians, are exempt from DSHEA. Most countries outside of the United States have even more prohibitions about the claims that can be made about 4Life products.