

FITNESS LABS™
NUTRITION CORPORATION

September 28, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

OCT 18 2004

Re: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

Fitness Labs Nutrition Corporation, P.O. Box 3896 Torrance, CA 90510-3896, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

“Whey protein is your ideal choice. It has the highest biological value of any protein. Gram for gram, your body uses it more efficiently than other protein sources.*”

“This highly concentrated protein is more than 98% undenatured, making it soluble. Solubility is key to better digestion and absorption.*”

“Our whey protein is 95% digestible. This makes it ideal for hungry muscles, which rely upon a steady supply of high quality protein.*”

“Quick digesting whey peptides! Each serving provides approximately 6 grams of low molecular weight whey peptides (4g are naturally occurring, 2g are added). The resulting preferred combination of peptides and longer chain proteins in whey delivers protein at various rates of absorption.*”

“You benefit from a wide spectrum of vital whey fractions. Gainer 500® preserves natural whey fractions, including alphalactalbumin – the form of protein found in human mother’s milk, and immunoglobulin fractions – which support the immune system. Plus, our whey retains glycomacropetides and another fraction containing a precursor to glutathione – a powerful antioxidant produced by the body.*”

“Approximately 7 grams or about 50% of the essential amino acids in each serving are branched chain amino acids (BCAAs). BCAAs can supply alternative muscle fuel which may help preserve lean muscle mass.*”

“Each serving contains 2 grams of glutamine from whey and glutamine peptides. Glutamine is vital to those who are growing, to athletes and those under stress.*”

89905

FITNESS LABS™

NUTRITION CORPORATION

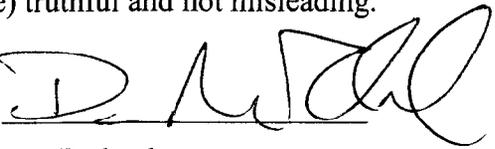
“For growing and maintaining muscle, make sure your hard earned muscle isn’t broken down and used for energy. Fuel your energy requirements from carbohydrates, not protein. Our first stage release system utilizes complex carbohydrates from corn hybrids (maltodextrin) for quick replenishment of glycogen (energy) stores and is rated medium to high on a glycemic index scale. Then fructose, a slower burning different type of carbohydrate is added for longer lasting energy. It’s a very low glycemic index carbohydrate with a 20 rating (for comparison – table sugar rates 59, honey is 87 and glucose is 100). Fructose is absorbed slowly and is ideal for endurance activities.*”

“Contains seven B complex vitamins, vital for protein metabolism and various enzymes that are critical for high energy levels.*”

“Enjoy Gainer 500® for a healthier body!.*”

These claims are being made for a product named Fitness Labs® Whey Protein Gainer 500®. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the Fitness Labs Nutrition Corporation and certifies that the information contained in this notice is complete and accurate, and that Fitness Labs Nutrition Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

By: 

Dan McFarland
President