

May 31, 2001

Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety & Applied Nutrition Food and Drug Administration 200 C Street SW Washington, D.C. 20204

Dear Sir or Madam:

This letter will serve as a 30-day notification, pursuant to 403 (r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Product Manufacturer:

Twin Laboratories, Inc. 150 Motor Parkway Hauppauge, NY 11788

Text of statement being made: "When taken orally as a dietary supplement, peptide-bonded amino acids (derived from pancreatic digests of protein) increase nitrogen retention sixteen times more than that of crystalline free form amino acid mixtures (Smith et al. 1982)."

Dietary supplement ingredients: Carnitine, Branched Chain Amino Acids (L-Leucine, L-Isoleucine, L-Valine), Peptide-Bonded and Free Amino Acids, Multi Vitamins, Minerals and Lipotropic Factors (fat metabolizers) Choline and Inositol, and Complex Carbohydrates.

Dietary supplement brand and name: Twinlab AMINO FUEL.

As required, enclosed are two photocopies of this notification.

The signee certifies that the information contained in this notice is complete and accurate, and that Twin Laboratories, Inc., has substantiation that the statement is truthful and not misleading.

Sincerely le sur chman

Executive Vice President Twin Laboratories, Inc.

Enclosures

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Twin Laboratories Inc., 150 Motor Parkway, Hauppauge, N.Y. 11788 • 631/467-3140 • Fax 631/630-3484