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December 12, 2000

Office of Special Nutritionals (HFS-450) 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 **30-day** notification pursuant to section 403 (r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Name and address of Dietary Supplement Manufacturer:

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

Text of statement being made: "Muscle Cell Volumizing Formula." "...complex carbohydrates-..stimulate the anabolic and anti-catabolic hormone insulin. Insulin enhances muscle growth by increasing the rate ammo acids enter muscle cells, Carbohydrates also increase the rate of muscle glycogen synthesis which is important for recovery."

Dietary supplement ingredients: Complex Carbohydrates, High Biological-Quality Milk and Egg Proteins, Branched Chain Ammo Acids (L-Leucine, L-Vaiine, and L-Isoleucine), Glutamine, Alpha-Ketoglutarate, and Creatine Monohydrate.

Dietary supplement brand and name: Twinlab Super GAINERS 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.

Singerery,

Neil Blechman

Executive Vice President

Twin Laboratories, Inc.

Enclosures

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