

Iovate Health Sciences U.S.A. Inc.

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

dec'd
JAN 7 2005

NOTIFICATION OF STATEMENT OF NUTRITIONAL SUPPORT

Dear Sir or Madam:

In accordance with Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 C.F.R. § 101.93, we hereby provide the following notice with regard to the marketing of the Dietary Supplement described below:

Distributor: Iovate Health Sciences U.S.A. Inc., 3880 Jeffrey Blvd., Blasdell, NY 14219

Name of Supplement: THERMOGAIN™

Statement of Nutritional Support:

- Ignite thermogenesis
- Build more muscle
- Crank up intensity
- That's why MuscleTech researchers worked tirelessly to develop a unique product that not only burns calories, but builds muscle *at the same time*. After innumerable product trials and prototypes, MuscleTech researchers have developed the world's first and most powerful musclebuilding thermogenic – THERMOGAIN.
- The THERMOGAIN formula, with both patented and patent-pending ingredient combinations, is incredibly powerful in igniting thermogenesis, building muscle and cranking up workout intensity. Only serious bodybuilders and athletes should use it. And best part is that THERMOGAIN starts working right after you take your first serving.
- THERMOGAIN is powered by ingredients that are scientifically proven to deliver results. With THERMOGAIN powering your workouts, you'll not be able to train with ferocious intensity, but will also be able to build massive muscle size with deep cuts! There is definitely no other thermogenic that even comes close to THERMOGAIN. It's the most innovative thermogenic supplement ever created.

To the best of my knowledge, the information contained in this notice is complete and accurate, and Iovate Health Sciences USA Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,



Shan Chaudhuri
Regulatory Affairs Manager
Date: Jan 4, 2005

90552

3880 Jeffrey Blvd., Blasdell, NY 14219

97S 0162

LET

15323