



1954 6 JAN 27 P2:21

Jan 18, 2006

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

**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: HYDROXYCUT® HARDCORE

Statement of Nutritional Support:

975 0162

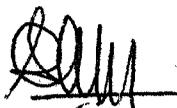
LET 17233

1. DECREASE BODYFAT BY 7.9%
2. INCREASE NOREPINEPHRINE BY 40%
3. MAXIMUM-STRENGTH THERMOGENESIS
4. Team MuscleTech™ researchers have invested in clinical studies to discover the most powerful formula ever to alter the way you burn fat. Hydroxycut® Hardcore makes all other fat burners obsolete. It is the most extraordinarily powerful fat burner ever developed.
5. Hydroxycut Hardcore utilizes an exclusive liquid Micro-dispersion Technology to deliver fat-burning components immediately to the body.
6. Hydroxycut Hardcore attacks the fat-burning process through a proprietary 5-step process to ensure maximum-strength fat loss. First Hydroxycut Hardcore elevates levels of norepinephrine - the key fat-burning hormone - by 40%. The second step involves ensuring norepinephrine levels remain elevated longer by drastically increasing cAMP levels. The third step involves alpha-receptor inhibition to ensure the fat-burning signal remains uninterrupted. The fourth step involves inhibiting the enzyme COMT, to ensure the fat-burning signal grows in strength. The fifth step involves producing heat (thermogenesis) by accelerating the breakdown of released fats in the mitochondria.
7. In a clinical study conducted at the University of Laval, subjects using the key components in Hydroxycut Hardcore burned significantly more calories per day than those using a placebo!
8. In a second clinical study, at a different institution, subjects reduced their bodyfat by a shocking 7.9%. In this study, subjects' visceral and subcutaneous fat levels were measured. After 12 weeks of treatment with the Hydroxycut Hardcore components, subjects experienced a 7.9% drop in bodyfat. That's astounding!

06-434

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,

A handwritten signature in black ink, appearing to read 'S. Chaudhuri', with a horizontal line underneath.

Shan Chaudhuri  
Regulatory Affairs Manager