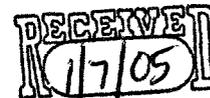


# Iovate Health Sciences U.S.A. Inc.

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



## 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: NITROXY3™

Statement of Nutritional Support:

- Enhances lean muscle growth, strength, and recovery
- Prolongs muscle pumps
- Supports endurance and stamina
- Promotes increased blood flow and circulation
- With the power of two scientifically designed proprietary blends – VASODILASE™ and STIMUGROW™ – specifically designed to enhance lean muscle growth and muscular pumps, and support endurance and stamina, patented and patent-pending NITROXY3 is an advanced performance-enhancing nitric oxide (NO) product that sits in a category of its own. NITROXY3 contains ingredients that have been shown to promote increased blood flow and circulation.
- To further enhance and extend the benefits of NITROXY3, the research team behind this innovative product has included the proprietary time-release technology AKG-EXTEND™. This time-release technology helps to prolong the effects of NITROXY3 for several hours.

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 "Shan Chaudhuri".

Shan Chaudhuri  
Regulatory Affairs Manager  
Date: Jan 4, 2005

3880 Jeffrey Blvd., Blasdell, NY 14219

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