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OCT 11 2006

Mr. Shan Chaudhuri
Regulatory Affairs Manager
Iovate Health Sciences U.S.A. Inc.
3880 Jeffrey Boulevard
Blasdell, New York 14216

Dear Mr. Chaudhuri:

This is in response to your letter of September 25, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Iovate Health Sciences U.S.A. Inc. is making the following claims for the product **Cold MD™**:¹

“Clinically Proven Immune System Support.”

“94% FASTER RECOVERY”

“Increased Immune System Resistance by 312%.”

“[C]old MD helps you recover an average of 94% faster.”

“Subjects were observed for two seasons. In this study, subjects reduced the frequency of episodes...reduced the duration of episodes....”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, including the name of the product (i.e., Cold MD) in the context of other claims made for the product, suggest that it is intended to treat, prevent, or mitigate a disease, namely, the common cold. These claims, including the name of the product (i.e., Cold MD), do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

¹FDA is also aware of print media advertising, using your trademark (i.e., Cold MD) with permission, promoting this product using explicit claims that it is intended to treat, prevent, mitigate, or cure colds and flu. Such representations are further evidence that the intended use of this product is as a drug.

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Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

IOVATE

September 25, 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

SEP 28 2006

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: Cold MD™

Statements of Nutritional Support:

1. Clinically Proven Immune System Support
2. 94% FASTER RECOVERY
3. CLINICALLY PROVEN RESULTS!
4. Increased Immune System Resistance by 312%
5. Provides maximum protection when used daily, and provides three great benefits for maximum immune system support.
6. All-in-one solution - Medical doctor formulated and approved, Cold MD delivers clinically proven immune system support. In addition, by supporting your immune system, Cold MD helps you recover an average of 94% faster. In fact, in a rigorous double-blind clinical study reviewed by a medical doctor, the powerful immune system support effects of Cold MD were validated.
7. 312% Increased Immune System Resistance: The exclusive formula supports a strong immune system with clinically proven ingredients, which results in 312% greater immune system resistance.
8. Just 1 convenient serving a day of 2 non-drowsy EZ-swallow sweet-coated caplets is all that's needed for ongoing clinically proven immune system support. Why continue to suffer unnecessarily? Cold MD is a clinically proven, all-in-one solution that works fast!
9. A clinical study was conducted on the key ingredient combination in Cold MD. Subjects were observed for two seasons. In this study, subjects reduced the frequency of episodes by an average of 3.3 vs. 0.8 against placebo (312% greater resistance), and reduced the duration of episodes by an average of 3.3 days vs. 1.7 days against placebo (recovered 94% faster).
10. "I've reviewed all the available research. In my opinion, Cold MD contains clinically proven ingredients and is a drug-free way to support a strong immune system and allow you to recover faster." Dr. Marvin Heuer, Medical Doctor, FAAFP, Iovate Chief Scientific Officer and MD Advisory Board Chair

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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