



AUG 25 2000

1729 10 SEP -5 2000

Ms. Muriel Orenga
Intelligent Nutrients
321 Lincoln Street, NE
Minneapolis, Minnesota 55413

Dear Ms. Orenga:

This is in response to your letter of August 14, 2000 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 Intelligent Nutrients is making the following claim, among others, for the product **Intelligent Nutrients Green tea polyphenols**:

“Helps maintain...cholesterol levels.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely, hypercholesterolemia. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

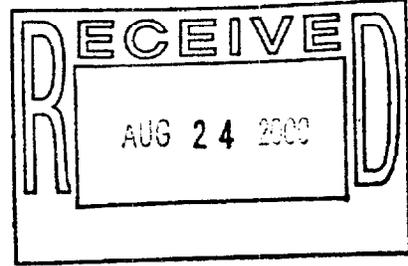
John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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August 14, 1999



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

**NOTIFICATION OF STATEMENT[S]
OF NUTRITIONAL SUPPORT**

This notification is filed pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 343(r)(6).

Name of dietary supplement	Intelligent Nutrients, "green tea polyphenols"
Dietary ingredients	Green tea extract
Statement[s] of nutritional support	~Helps protect body's cells and tissues by neutralizing free radicals ~Helps maintain cardiovascular health and cholesterol levels

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading.

By Muriel Oseaga
Muriel Oseaga