



NOV 13 1996

Mr. Gianna di Franco
Registration Manager
Quantum, Inc.
754 Washington Street
Eugene, Oregon 97401

Dear Mr. di Franco:

This is in response to your letter of September 11, 1996 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are marketing a product called "Cold & Flu" in both a 2 oz size and a 30 capsule size and are making the following claim about this product

Nutritional Support for Cold & Flu.

Section 403(r)(6) of the act 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. Using the name of diseases such as cold and flu in the product's name and making a claim that this product is for nutritional support for cold and flu suggest that this product is intended to mitigate, treat, cure, or prevent these specific diseases. Thus, the product is subject to regulation under the drug provisions of the act. If you intend to use specific disease names in the name of your product and 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.

97S-0163

LET 30

Page 2 - Mr. Gianna di Franco

Please contact us if we may be of further assistance.

Sincerely yours,

**James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition**

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Seattle District Office, Office of Compliance, HFR-PA300

**FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement,**

HFC-200

QUANTUM, INC.
754 WASHINGTON ST.
EUGENE, OR 97401



(541) 345-5556
FAX (541) 345-9796
1 (800) 448-1448
[HTTP://WWW.HEALTHSITE.COM/QUANTUM](http://www.healthsite.com/quantum)

Elizabeth A. Yetley, Ph. D. (HFS-450)
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C. St., S.W., Room 2804
Washington, D.C. 20204

September 11, 1996

Dear Dr. Yetley,

Pursuant to the requirement of DSHEA, Quantum, Inc. hereby informs you of the following structure and function claim which it is making on its product:

Product: Cold & Flu - 2 oz.
Claim: Nutritional Support for Cold & Flu
Date: September 11, 1996

Sincerely,


Gianna di Franco
Registration Manager