



MAR 13 1998

Rec'd 3/26/98 jh

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

Dear Ms. di Franco:

This is in response to your letters of September 11, 1996 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 Quantam, Inc. is making the following claims, among other claims, for the products:

Elderberry Extract - 2 oz.

"Nutritional Defense Against Cold and Flu Season"

Standardized Elderberry Extract - 60 Capsules

"Nutritional Defense Against Cold and Flu Season"

Elderberry C-Syrup - 4 fl. oz.

"Nutritional Defense Against Cold and Flu Season"

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 these products suggest that they are intended to prevent, treat or mitigate a disease, namely the common cold and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to

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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,

**James T. 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, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340**

cc:

**HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456;jel:3/13/98:docname:48644.adv:disc26**

QUANTUM, INC.

754 WASHINGTON ST.

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONAL HFS-450



(541) 345-5556

FAX (541) 345-9796

1 (800) 448-1448

HTTP://WWW.HEALTHSITE.COM/QUANTUM

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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: Elderberry Extract - 2 oz.

Claim: Nutritional Defense Against Cold and Flu Season

Date: September 11, 1996

Sincerely,

Gianna di Franco
Gianna di Franco
Registration Manager

28644

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



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[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: Standardized Elderberry Extract - 60 Capsules

Claim: Nutritional Defense Against Cold and Flu Season

Date: September 11, 1996

Sincerely,

Gianna di Franco
Gianna di Franco
Registration Manager

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



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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: Elderberry C-Syrup - 4 fl. oz.

Claim: Nutritional Defense Against Cold and Flu Season

Date: September 11, 1996

Sincerely,

Gianna di Franco
Gianna di Franco
Registration Manager