



APR - 7 1999

9 0 0 1 '99 APR 20 P2:13

Joseph J. Vitale, Sc.D., M.D.
Mallory Institute of Pathology
Boston University School of Medicine
784 Massachusetts Avenue
Boston, Massachusetts 02118-2394

Dear Dr. Vitale:

This is in response to your letter of March 29, 1999, to the Food and Drug Administration (FDA) regarding claims you intend to make on a product marketed as a dietary supplement. It is not clear whether your letter is intended to be the submission required pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93(a), nonetheless, FDA will treat your letter as the required submission and the certification by you that the information contained in the notice is complete and accurate, and that you have substantiation that the statement is truthful and not misleading (see 21 CFR 101.93(a)(3)).

A statement included in labeling under the authority of 21 U.S.C. 343(r)(6) may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. Your submission states that you intend to, as part of the claims for your product, include citations to one or more articles published in research journals or other sources. The use of citations that contain references to the role of a substance or product in treating, preventing, curing, or mitigating disease may suggest that a product is intended to treat, cure, prevent, or mitigate disease. Such claims do not meet the requirements of 21 U.S.C. 343(r)(6). Such claims suggest that a 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

FDA proposed regulations in the April 29, 1998, Federal Register (63 FR 23624) to define the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The agency has not yet finalized that proposal. However, in the context of that rulemaking, we are actively considering what should and should not be a disease claim. Therefore, our current view about what claims, including the use of citations to published articles, are permitted under 21 U.S.C. 343(r)(6) may change as we develop a final rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body.

975-0163

LET 265

Page 2 - Dr. Joseph J. Vitale

We hope this information is helpful.

Sincerely,

Lynn A. Larsen, Ph.D.
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, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey)

HFV-228 (SBenz)

HFV-232 (ABrown)

f/t:HFS-456:rjm:4/7/99:docname:64492.adv:disc36

Boston University School of Medicine

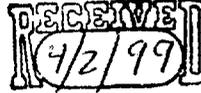
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64492



Joseph J. Vitale, Sc.D., M.D.
Director, Nutrition-Pathology Unit



March 29, 1999

Dr. Lynn Larson
Director, Programs and Enforcement Policy
Office of Special Nutritionals
HFS 455
FDA 200 C Street, SW
Washington, D.C. 20204

Dear Dr. Larson:

I am writing you as an interested party, as a Trustee of the Boston International Foundation for Medical Education and on the advice of counsel, notifying you of our intention to market a Structure/Function Claim for a dietary supplement, a lecithin, albeit highly purified, phosphatidyl choline (PC - 95%) with minimum amounts of other phosphatides.

The Claim reads as follows: "**PC-95 has been shown to enhance host defenses and immune functions in both animals and humans**". References to relevant literature, published in well recognized and respected medical journals will be included for the consumer.

For your information, I have enclosed two items related to PC-95, a copy of the most recent Patent and a copy of a publication. As an aside, PC-95 (we have labelled ABVA-1) has the potential for use in several clinical entities (please exam and read various sections of the Patent).

Best wishes.

Sincerely,

Joseph J. Vitale
Professor of Pathology and Laboratory Medicine
Professor of Community Medicine

JJV:mgr