



MAR 17 1998

Rec'd 3/26/98 jb

Mr. Larry Sayage
Vice President
Action Labs
280 Adams Boulevard
Farmingdale, New York 11735

Dear Mr. Sayage:

This is in response to your letter of June 5, 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 Action Labs is making the following claim for the product Echinacea/Golden Seal: "Helps promote well-being during 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 statement that you are making for this product suggests that it is intended to prevent, treat or mitigate disease, namely the common cold and influenza. 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,

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, New York District Office, Office of Compliance, HFR-NE130

975-0163

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, KCarson)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:3/12/98

Init:GCF-1:LNickerson:3/12/98

f/t:HFS-456:rjm:3/17/98:docname:46905.adv:disc27



'96 JUN 10 P3:36

June 5, 1996

Mr. John Gordon
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals (HFS-456)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

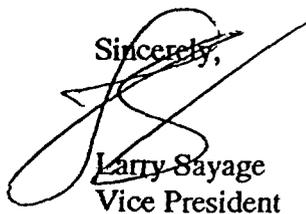
Dear Mr. Gordon:

This responds to your letter of April 18, 1996 concerning our notification dated February 8, 1996 under section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act (FDC Act) for our product Echinacea/Golden Seal. We have received the label for this product to change the statement of nutritional support to "Helps promote well-being during cold and flu season."

FDA has received several notifications of statements of nutritional support for dietary supplements of echinacea bearing statements similar to this one. See, e.g., notification of June 21, 1995 from natures Way ("helps promote general well-being during cold and flu season") and notifications of September 8, 1995 from NaturaLife ("helps promote general well-being during cold and flu season"). Since, to the best of our knowledge, FDA has not objected to the notifications filed by these companies, we assume this alternative claim is acceptable to the agency as a statement of nutritional support, provided all applicable requirements of the FDC Act are met.

Please consider this letter as the notification required by section 403 (r) (6) of the FDC Act for this new statement of nutritional support to be made for our Echinacea/Golden Seal product. We expect to begin distributing the newly labeled product on July 1, 1996.

Sincerely,



Larry Sayage
Vice President

cc: FDA, New York District Office, Office of Compliance
FDA, Center for Drug Evaluation and Research, Office of Compliance

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