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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

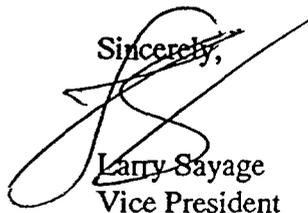
Dear Mr. Gordon:

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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