

APR 18 1996

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

Dear Mr. Sayage:

This is in response to your letter of February 8, 1996 making a submission 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 making the following statement of nutritional support for the product "Echinacea/Golden Seal."

For Relief of Symptoms of Cold, Flu and Sore Throats.

We would point out that 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. The statement that you are making for "Echinacea/Golden Seal" suggests that this product is intended for one of these purposes, in that it evidences that the product is intended for relief of symptoms of cold, flu, and sore throats. Therefore, this claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for other than food use within the meaning of section 201(g) of the act and that it is subject to regulation under the drug provisions of the act. Furthermore, it appears that this product is intended for drug use within the meaning of section 201(g)(1)(B) 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.

Sincerely yours,

John Gordon
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

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