

APR 29 1996

Ms. Diane Harper
Director, Nutrition & Regulatory Affairs
Nature's Life
Garden Grove, CA 92641-3914

Dear Ms. Harper:

This is in response to your letter of March 12, 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 in the labeling of the product "Echinacea."

Echinacea also stimulates wound healing by increasing fibroblasts (blood-clotting cells).

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" suggests that this product is intended to mitigate, treat, or cure a disease, in that it claims to "stimulate wound healing by increasing fibroblasts (blood-clotting cells)." This claim does not meet the requirements of section 403(r)(6) of the act. The 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 a claim 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 yours,

James T. Tanner
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

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