



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JUL 3 1996

Mr. Gale Bensussen  
President  
Leiner Health Products  
901 E. 233rd Street  
Carson, California 90745-6204

Dear Mr. Bensussen:

This is in response to your letter of May 29, 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 statements for your products:

**"Your Life® Echinacea and Goldenseal"**

Supports immune system

Echinacea contains phenolic compounds which stimulate the growth of the body's own immune system. Goldenseal contains alkaloids which help to reduce excess mucous that may be found in the upper respiratory, nasal and ear passages. These supplements are important during the cold season for support of normal respiratory and sinus function.

**"Your Life® Dong Quai"**

Menstrual Discomfort

In traditional Asian medicine, dong quai is an important herbal tonic for women. Aromatic compounds, coumarins and essential oils- considered the main active ingredients - have been shown to help normalize uterine contractions and to minimize discomfort associated with the monthly cycle.

**"Your Life® Ginger"**

Aids digestion

Ginger is a root which has world wide usage as an aid to digestive activity. As a supplement, it's unique compounds can help offset the distresses which cause stomach discomfort from motion or certain foods.

We would point out that section 403(r)(6) of the act makes it 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. Yet, the statements that you are making for these products suggest that they are in fact intended to treat or mitigate a disease. "Your Life® Echinacea and Goldenseal" claims that it stimulates the body's immune system, helps reduce excess mucous that may be found in the upper

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respiratory, nasal and ear passages, and is important during the cold season for support of normal respiratory and sinus function. Taken together, these statements suggest that the product is intended for the prevention and treatment of colds. "Your Life® Dong Quai" claims that it is a traditional Asian medicine, suggesting that the product is intended for the treatment of menstrual pain. "Your Life® Ginger" claims that it offsets the distresses which cause stomach discomfort from motion or certain foods, suggesting that it is intended to treat or mitigate nausea. Therefore, these claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for other than food use within the meaning of section 201(g) of the act, and that they are subject to regulation under the drug provisions of the act. Thus, it appears that these products are 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,

James 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, Los Angeles District Office, Office of Compliance, HFR-PA200  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200