



NOV 14 1996

Mr. Scott Rexinger
Senior Vice President,
Product Marketing & Development
Leiner Health Products
901 E. 233rd Street
Carson, California 90745-8400

Dear Mr. Rexinger:

This is in response to your letter of October 18, 1996 to the Food and Drug Administration (FDA). Your letter responds to a letter from FDA dated July 3, 1996, in which FDA stated that Leiner Health Products was making drug claims for their products. Your October 18, 1996 letter stated that Leiner Health Products is revising the claims for their products to the following:

"Your Life® Echinacea and Goldenseal"
Supports immune system.

Animal and laboratory studies show that echinacea stimulates the body's own immune system,[sic] Scientists discovered that alkaloids like those found in Goldenseal helped to reduce excess mucous production. These supplements are important during the cold season.

"Your Life® Dong Quai"
Menstrual Discomfort.

Dong Quai, with its aromatic compounds, coumerins and essential oils has long been used to help normalize uterine contractions and to minimize discomfort associated with the monthly cycle

Your Life® Ginger
Aids digestion.

Ginger is a root that has world-wide usage as an aid to normal digestive activity. As a supplementation, its unique aromatic compounds can also help offset the distresses that cause stomach discomfort from motion.

As stated in our previous letter, section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act) makes it clear that a statement included in labeling under the

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authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The revised 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" continues to claim that it stimulates the body's immune system, helps reduce excess mucous production, and is important during cold season. Taken together, these statements suggest that the product is intended for the prevention and treatment of colds. "Your Life® Dong Quai" continues to claim that it is intended for the treatment of menstrual pain. "Your Life® Ginger" continues to claim that it offsets the distresses which cause stomach discomfort from motion, suggesting that it is intended to treat or mitigate motion sickness. 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



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October 18, 1996

James Tanner, Ph.D.
Office of Special Nutritionals (HFS-455)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.,
Washington, D.C. 20204

Dear Dr. Tanner:

Your letter of July 3 to Mr. Bensussen arrived when Leiner was already engaged in a reevaluation of both the scientific support and wording of its claims for dietary supplements for which Section 403(r)(6) notifications had been submitted to FDA. The purpose of this action was to reassure ourselves that our support for the claims was up to date. Rather than respond to your letter immediately we decided it would be preferable to complete our review. This has now been done, and, where needed, supplemental Section 403(r)(6) submissions will be made for Leiner Products.

Before responding to your comments with regard to the three specific dietary supplements noted in your letter, it may be useful to outline Leiner's approach to compliance with Section 403(r)(6).

That section of the Act, in addition to claims for classical nutrient deficiency disease, permits a claim that

- "describes the role of a ... dietary ingredient intended to affect the structure or function in humans,"
- "characterizes the documented mechanism by which a ...dietary ingredient acts to maintain such structure of function," or
- "describes general well-being from consumption of a ... dietary ingredient."

In addition, such a statement "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease...." (Emphasis added).

For the reasons outlined below, it is Leiner's view that the claims made for each of the products discussed in your letter falls within the boundaries of Section 403(r)(6).

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1. *Your Life*® Echinacea and Goldenseal.

The statement quoted in your letter is:

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.

The revised statement for this product is as follows:

"Supports immune system.

Animal and laboratory studies show that echinacea stimulates the body's own immune system. Scientists discovered that alkaloids like those found in Goldenseal helped to reduce excess mucous production. These supplements are important during the cold season."

We believe that this revised statement carefully tracks the "documented mechanism" by which these ingredients help "to maintain" normal bodily functions. In addition, we disagree with your suggestion that this product promotes the mitigation of any "specific disease."

2. *Your Life*® Dong Quai.

The statement quoted in your letter is:

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.



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The revised statement for this product is as follows:

"Menstrual Discomfort.

Dong Quai, with its aromatic compounds, coumerins and essential oils has long been used to help normalize uterine contractions and to minimize discomfort associated with the monthly cycle."

Neither menstruation nor its commonly associated pain is a "disease" and thus the claim which discusses mechanisms for maintaining normal function as well as promoting general "well-being" also falls squarely within Section 403(r)(6) of the Act.

3. *Your Life*[®] Ginger.

The statement quoted in your letter is:

Aids digestion

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

The revised statement for this product is as follows:

"Aids digestion.

Ginger is a root that has world-wide usage as an aid to normal digestive activity. As a supplementation, its unique aromatic compounds can also help offset the distresses that cause stomach discomfort from motion."

Your comment is addressed solely to the original version of the second sentence. We do not believe that the discomfort resulting from motion is an "illness," but rather reflects normal range of functioning of the body that can be addressed by the aromatics in ginger, thus falling within the "role" clause of the permitted claims under Section 403(r)(6).

Prior to the enactment of DSHEA, it was not necessary for FDA carefully to distinguish between claims of "disease" (covered by Section 201(g)(1)(B) of the Act) and claims that an article, other than traditional food, was intended to "affect the structure or any function" of the body (Section



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201(g)(1)(C). Since the passage of DSHEA, documented claims in the latter category are appropriate "nondrug" claims and in their various manifestations fall within the scope of Section 403(r)(6). It is only "disease" claims that are precluded. We believe that FDA has not been precise in recognizing the distinction between ailments commonly of exogenous origin,, i.e., disease, and temporary variations in the normal functioning of the body, including non-disease related claims concerning menstruation, over-exertion, and many other "structure or function" conditions.

Leiner appreciates the consideration that the Agency is giving to these submissions. We have instituted systems designed to assure that the claims we make are appropriately substantiated and limited to the scope permitted by Section 403(r)(6).

Sincerely,

LEINER HEALTH PRODUCTS

Scott Rexinger
Senior Vice President,
Product Marketing & Development