

AUG 26 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 July 9, 1996 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 on the labels or in the labeling of your product Your Life® Folic Acid 400 mcg:

Adequate folate in a healthful diet may reduce a woman's risk of having a child with brain or spinal cord birth defect. Studies show folate helps men and women maintain normal cardiovascular system function.

Part of this statement (i.e., Adequate folate in a healthful diet may reduce a woman's risk of having a child with brain or spinal cord birth defect) is not a statement of nutritional support subject to section 403(r)(6) of the act, but is a health claim subject to section 403(r)(1)(B) of the act. A "health claim" is defined in Title 21 of the Code of Federal Regulation (21 CFR) (21 CFR 101.14(a)(1)) as any claim made on the label or in labeling of a food that "characterizes the relationship of any substance to a disease or health-related condition." This statement characterizes the relationship between folate and brain or spinal cord birth defects. When making a health claim on the label or in the labeling about the relationship between folate and neural tube defects, you must comply with section 403(r)(1)(B) of the act and all appropriate implementing regulations (see 21 CFR 101.79).

The second part of this statement (i.e., Studies show folate helps men and women maintain normal cardiovascular system function) is not a part of the optional information allowed as a part of this health claim. This part of the claim is a statement of nutritional support and, as such, must be made in accordance with section 403(r)(6) of the act. Section 403(r)(6)(C) of the act requires that statements of nutritional support contain "prominently displayed and in boldface type, the following: 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.'"

Thus, you are making two different types of claims in this statement. The "health claim" must be made in accordance with section 403(r)(1)(B) of the act. The "statement of nutritional support" must be made in accordance with section 403(r)(6) and must bear the disclaimer required by section 403(r)(6)(C) of the act to distinguish it from a "health claim" which has been authorized by FDA.

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Please contact us if we may be of further assistance.

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**