

JUL 30 1996

Dr. Luke R. Bucci
Weider Nutrition Group
1960 South 4250 West
Salt Lake City, Utah 84104-4836

Dear Dr. Bucci:

This is in response to your letter of April 9, 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:

“Schiff All Natural Echinacea Cold Season Formula (180t)”

Echinacea root extracts may improve number and functions of immune system cells in humans. Resistance to viruses may be enhanced.

“Schiff Phytocharged Lycopene 5mg (softgels)”

Eating a diet high in tomatoes and foods rich in tomato extracts (tomato sauce) has been related to a lower risk of prostate and other cancers. Tomatoes contain lycopene, a carotenoid that is an efficient defense against singlet oxygen, a molecule that damages cells.

The statement that you are making for “Schiff Phytocharged Lycopene” (i.e., Eating a diet high in tomatoes and foods rich in tomato extracts (tomato sauce) has been related to a lower risk of prostate and other cancers) appears to be an unauthorized health claim. Thus, this statement may subject this product to regulatory action under the food misbranding provisions of the act and to regulation as a drug. A “health claim” is defined in 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.” The statement that you are making characterizes the relationship between a diet high in tomatoes and in foods rich in tomato extracts (tomato sauce) and prostate and other cancers and thus, would be subject to the health claim provisions of section 403(r)(1)(B) of the act. For this claim to be legally used on the label or in the labeling of a dietary supplement, you must submit an appropriate health claim petition to the FDA, and claims about the substance/disease relationship would have to be authorized by the agency.

Further, the statements that you are making suggests that the products that bear the claims are intended to prevent disease, in that: (1) “Schiff All Natural Echinacea Cold Season Formula (180t)” claims that it may enhance resistance to viruses and (2) “Schiff Phytocharged Lycopene 5mf (30 softgel)” claims to lower the risk of prostate and other cancers. 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. Therefore, these claims do not meet the requirements of section 403(r)(6) of the act. These

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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. 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, Denver District Office, Office of Compliance, HFR-SW200

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200