



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

4347 01 MAY 15 P2:30  
MAY - 1 2001

Dennis M. Gronek, Esq.  
Gronek & Armstrong  
98th Floor - Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606

Dear Mr. Gronek:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 29, 2001 on behalf of Premier Direct, Inc. In your letter, you stated that Premier Direct, Inc. disagrees with FDA's view that certain claims that we identified in a letter dated March 21, 2001 suggest that certain of their products are intended to treat, prevent, cure, or mitigate disease. You stated that the label claims we cited in our letter are equivalent to the claim of the type "helps to maintain cholesterol levels that are already within the normal range," a claim that FDA sanctioned in the preamble language to the January 6, 2000 final rule (65 FR 1000 at 1018).

You are correct that FDA concluded that not all claims related to cholesterol are disease claims under the Federal Food, Drug, and Cosmetic Act (the Act). In the preamble to the final rule, FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid making a cholesterol maintenance claim into an implied claim, a cholesterol maintenance claim would have to explicitly disclaim the implied ability of the product to prevent the development of elevated cholesterol levels or to reduce an elevated cholesterol. Therefore, an appropriate structure/function claim about maintaining cholesterol should explicitly state that the cholesterol levels that are the subject of the claim are "already within the normal range." We believe that this criteria also applies to claims about blood pressure and blood glucose levels, and therefore, a similar contextual qualification would be appropriate for claims about blood pressure and blood glucose levels in order to make them appropriate structure/function claims.

In the March 21, 2001, letter to Premier Direct, Inc., we informed the firm that we consider the claims "maintain cholesterol levels within a normal range," "maintain blood pressure levels within a normal range," and "maintain blood sugar levels within a normal range" to be implied claims to treat, prevent, cure, or mitigate diseases, namely, hypercholesteremia, hypertension, and abnormal blood glucose levels. Your March 29 letter does not change our view. We do not believe that the meaning of "to maintain normal" conveys the same meaning as "maintain levels that are already normal" with respect to the meaning it conveys when used in a claim about the effect of a product on blood cholesterol (or blood pressure or

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blood glucose) because the former claim does not clearly disclaim the implicit effect that the maintenance of normal levels is achieved by reducing an elevated cholesterol level. For this reason, we are not persuaded that the conclusion expressed in our March 21, 2001 letter is incorrect and we stand by our original determination that the claims proposed in your original submission are disease claims that subject your products to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

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

FDA, Florida District Office, Compliance Branch, HFR-SE240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-8 10 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson).

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75302  
March 29, 2001

John B. Foret, Director  
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Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
Washington, DC 20204

APR - 2 2001

Re: March 21, 2001 Courtesy Letter

Dear Mr. Foret:

This firm represents Premier Direct, Inc., Delray Beach, Florida. Our client has requested that we respond to your March 21, 2001 courtesy letter.

In your letter, you object to the claims "...maintain cholesterol levels within a normal range" made in relation to the Cordyceps, Garlic-Odorless, and Green Tea products, "...maintain blood pressure levels within a normal range" made in relation to the Hawthorn Berry Extract, and Potassium Vanadyl Sulfate products, and "...maintain blood sugar levels within a normal range" made in relation to the Vanadyl Sulfate and Gymnema Sylvestre products. We disagree that these claims represent these products for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

The preamble to the final regulation concerning structure/function claims for dietary supplements (January, 2000) stated, in the discussion concerning signs or symptoms of disease, that in determining whether a statement is a structure/function claim or a disease claim, the focus should be placed on whether the labeling suggests that the product will produce a change in the characteristic signs or symptoms of a specific disease or class of diseases (e.g., "lower cholesterol" or "lower blood pressure"). It also was stated that there is no intention to preclude structure/function claims that refer to the maintenance of normal or healthy structure or function. Such claims do not imply disease unless presented in a context in which other statements or pictures in the labeling imply disease treatment or prevention.

We are unaware of any disease associated with normal cholesterol levels, normal blood pressure levels or normal blood sugar levels. Therefore, a claim that a product maintains, not increases or decreases, cholesterol levels, blood pressure levels or blood sugar levels within a normal range does not refer to any disease or any sign or symptom of a disease.

In addition, the labeling statements were not made in conjunction with other label statements or pictures that imply disease or even abnormality. Accordingly, the statements made by our client fall within the universe of acceptable structure/function claims, not "drug" claims.

In the preamble, the FDA explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, and that it believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. The FDA cited as an appropriate structure/function claim for maintaining cholesterol, "helps maintain cholesterol levels that are already within a normal range." We believe an analogous claim would also be applicable to blood pressure levels and blood sugar levels.

The claims made by Premier Direct in relation to its products are substantially the same as the statement cited by the FDA as an appropriate structure/function claim. Also, it should be noted that in a three-person FDA panel discussion concerning the structure/function claim regulation, Dietary Supplements Branch Acting Chief Robert Moore discussed the difference between structure/function claims and disease claims concerning cholesterol. In differentiating between these claims Dr. Moore rejected "fiber helps promote healthy cholesterol" as a disease claim but approved the statement "soy protein helps maintain cholesterol levels within a normal range" as a legitimate structure/function claim. The claim approved by Dr. Moore is the same claim used by Premier Direct for its products. Dr. Moore also stated that similar logic would apply to blood pressure. We see no reason why similar logic would not also apply to blood sugar.

In sum, the statements made in connection with the Premier Direct product labels are entirely consistent with structure/function claims permitted for dietary supplements under DSHEA, 21 CFR §101.93 and public statements by a prominent FDA official. Quite frankly, we are at a complete loss as to how you could summarily conclude that they are "disease" claims.

Please provide us with further information concerning your summary conclusion that "...maintain cholesterol levels within a normal range", "...maintain blood pressure levels within a normal range", and "...maintain blood sugar levels within a normal range" are disease

claims. Until we receive some reasonable explanation that enables us to reconcile your conclusion with the regulation, its preamble and well-publicized comments from prominent FDA officials, we simply cannot recommend any modifications to those label statements.

Sincerely yours,  
GRONEK & ARMSTRONG

A handwritten signature in cursive script, appearing to read "Dennis M. Gronek".

Dennis M. Gronek

DMG:  
pr

CC: Premier Direct, Inc.