



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

7906 '01 JUN 11 P2:05

MAY 31 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 May 14, 2001 on behalf of Premier Direct, Inc. In your letter, you reiterate your disagreement 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.

We are not persuaded that the agency's conclusion that the claims that were the subject of our March 21, 2001 letter are disease claims is incorrect. Moreover, our letter of May 1, 2001 stands as our explanation about how we reached that conclusion. We believe that the subject claims are disease claims that subject the products to regulation under the drug provisions of the Act. A firm uses such claims at the risk that they may subject the product to regulatory action by the agency.

Please contact us if we may be of further assistance.

Sincerely,

for Robert Moore

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

97S 0163

LET 506

Page 2 - Mr. Dennis M. Gronek

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

Page 3 - Mr. Dennis M. Gronek

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

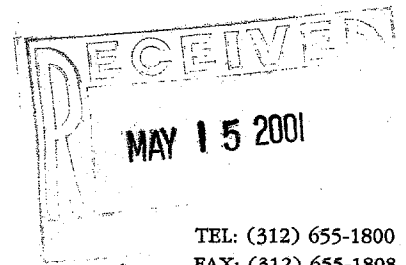
f/t:5/29/01:docname:75964.adv:disc56

GRONEK & ARMSTRONG

ATTORNEYS AT LAW

98TH FLOOR - SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606

DENNIS M. GRONEK
ROBERT E. ARMSTRONG
PAUL J. WISNIEWSKI
DEBORAH L. RUSS
JACQUELINE P. KULER



TEL: (312) 655-1800
FAX: (312) 655-1808

May 14, 2001

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

75964

Re: March 21, 2001 Courtesy Letter

Dear Mr. Foret:

As previously indicated, this firm represents, Premier Direct, Inc., Delray Beach, Florida. The following is a response to your May 1, 2001 letter in which you responded to our comments concerning your March 21, 2001 Courtesy Letter objecting to claims made in relation to our client's Cordyceps, Garlic-Odorless, Green Tea, Hawthorn Berry Extract, Potassium Vanadyl Sulfate and Gymneama Sylvestre products. We continue to disagree with your position concerning the claims "...maintain cholesterol levels within a normal range", "...maintain blood pressure levels within a normal range" and "...maintain sugar levels within a normal range."

In your May 1, 2001 letter you inaccurately represent our comments to your Courtesy Letter by contending that we stated that the label claims cited are equivalent to the claim "helps maintain cholesterol levels that are already within the normal range." Nowhere in our letter did we state that the claims you objected to were "equivalent" to the claim approved by the FDA in the preamble of the final regulation concerning structure/function claims. Rather, we stated that the claims you objected to were "substantially the same as the statement cited by the FDA as an appropriate structure/function claim." We maintain that position.

The claim "helps maintain cholesterol levels within a normal range" conveys the same meaning as the claim "helps maintain cholesterol levels that are already within a normal range". The phrase "...that are already..." does not add any meaning that is not already conveyed in the claim "helps maintain cholesterol levels within a normal range". According to Webster's Dictionary, the term "maintain" means "to keep in an existing state". Therefore, when cholesterol is maintained within a normal range, it is, by definition, kept within a normal range. It is implied that cholesterol levels began in a normal range (i.e., are already within a normal range) and ended in a normal range.

Further, in the preamble to the final regulation concerning structure/function claims, the FDA stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims. As an example of a cholesterol claim which the FDA would consider an appropriate structure/function claim, the FDA provided "helps maintain cholesterol levels that are already within the normal range". Nowhere does the FDA state that this is the only acceptable cholesterol claim or that a cholesterol claim which does not contain the phrase "...that are already..." would not be an acceptable structure/function claim. Therefore, we request that you provide us with a coherent explanation of why the phrase "...that are already..." must be included in the claim "helps maintain cholesterol levels within a normal range" in order for the claim to be acceptable and how the phrase "...that are already..." substantially changes the meaning of the claim "helps maintain cholesterol levels within a normal range". Also, please provide your reasoning for objecting to the same claims for blood sugar and blood pressure.

In your May 1, 2001 letter you inaccurately represent the FDA's position in the preamble to the final regulation concerning structure/function claims. In your letter you concede that in the preamble the FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. You then claim that the FDA stated 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 elevated cholesterol. You then continue to state that 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".

Not only is your representation of the FDA's position inaccurate, it is inconsistent. In reality the FDA stated:

"Although many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease, normal cholesterol levels play a positive role in maintaining a healthy body. Cholesterol is a necessary constituent of cell membranes and of myelin, the sheath that coats nerves. Cholesterol is also required for the synthesis of steroid hormones, which are essential for life. Finally, cholesterol is required for the production of bile in the liver, making possible absorption of dietary fat and fat soluble vitamins."

The FDA then proceeded to provide, as an example of a claim which does not necessarily imply disease treatment, "helps maintain cholesterol levels that are already within a normal range." The FDA does not represent, explicitly or impliedly, that this is the only cholesterol claim that it will accept, and in fact, it stated that it believes that Congress intended to permit dietary supplements to carry claims "of this type" under section

403(r)(6)(A) of the Federal Food, Drug and Cosmetic Act.

Nowhere does the FDA state, as you represent, that in order to avoid making a cholesterol maintenance claim into an implied disease 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. As conveyed in the quotation reproduced above, the FDA's position concerning cholesterol is the opposite of what you are arguing. The FDA believes that, while many people think of cholesterol only in negative terms, that this belief is unfounded and untrue and that cholesterol plays several positive roles in maintaining a healthy body. According to the FDA, and contrary to your position, cholesterol maintenance does not necessarily imply disease (the FDA explicitly states, and you conceded that, "FDA does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims"), and therefore, unless a claim is explicitly made that a product prevents the development of elevated cholesterol levels or reduces elevated cholesterol, then it should not be considered a disease claim. Also, your position does not make sense because the claim approved as an example of an appropriate structure/function claim by the FDA (i.e., "helps maintain cholesterol levels that are already within a normal range") does not *explicitly* disclaim the implied ability of the product to prevent the development of elevated cholesterol levels or to reduce elevated cholesterol.

In your May 1, 2001 letter you state that the FDA does 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 cholesterol 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. Your argument is misplaced and misrepresents our client's claims and the FDA's position concerning the making of cholesterol claims.

Our client does not make the claim that its products "maintain normal" cholesterol, blood sugar or blood pressure levels. Rather, our client submitted the claim "helps maintain cholesterol (blood sugar, blood pressure) levels within a normal range". Also, nowhere does the FDA state that a claim must *explicitly* disclaim that the maintenance of normal levels is not achieved by reducing an elevated cholesterol level. In fact, as stated above, the FDA has explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims. Also, we believe that your inaccurate argument against the "to maintain normal" claims would apply equally to "maintain levels that are already normal" claims since, according to your words, such claims also do not *explicitly* disclaim the implicit effect that the maintenance of normal levels is achieved by reducing an elevated cholesterol level. Your reasoning is inconsistent with the FDA's position and inconsistently applied to claims which convey the same meaning.

Also, in your May 1, 2001 you failed to address the fact, which was clearly conveyed in our March 29, 2001 letter, that Robert Moore, Dietary Supplements Branch Acting Chief approved the claim "soy protein helps maintain cholesterol levels within a normal range" in a three-person FDA panel discussion concerning the structure/function claim regulation. Moore also stated that similar logic would apply to blood pressure. We are still awaiting your reasoning why similar logic would not apply to blood sugar.

We maintain our position that the claims "...helps maintain cholesterol levels within a normal range...", "...helps maintain blood pressure levels within a normal range..." and "...helps maintain blood sugar levels within a normal range..." do not suggest or imply disease treatment or prevention, and therefore, are not disease claims.

Sincerely,
GRONEK & ARMSTRONG

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

Dennis M. Gronek

CC: Premier Direct, Inc.