



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 18 2001 01 JUL -2 P1 58

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 letters to the Food and Drug Administration (FDA) dated May 4, 7, and 8, 2001 on behalf of Horizon Nutraceuticals, Santa Cruz, California, Source Naturals, Scotts Valley, California, and Planetary Formulas, Soquel, California. In your letters, you stated that the firms disagree with FDA's view that certain claims regarding the effects of the products on blood cholesterol (Guggal Cholesterol Compound (Planetary Formulas), Cholesterin (Horizon Nutraceuticals), Phytosterol Complex, Phytosterol Complex with 108 mg beta-sitosterol, Cholestrex, Wellness Garlicell, and Omega EPA (Source Naturals)), blood pressure (Potassium, K-Mag C, Calcium & Magnesium Chelate (Source Naturals)), blood sugar (Dura-Carb) (Source Naturals)), coronary blood flow (HeartResponse) (Source Naturals)), wound healing (OptiZinc) (Source Naturals) that we identified in our letters sent in response to the firms' various submissions made pursuant to 21 U.S.C. 343(r)(6) suggest that certain of their products are intended to treat, prevent, cure, or mitigate diseases.

In the preamble to the final rule on structure or function claims for dietary supplements (see 65 FR 1000 at 1018), 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

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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 various letters to your clients described above, we informed the firms that we consider the claims the notified us about regarding maintenance of cholesterol, blood pressure, and blood glucose levels were implied claims to treat, prevent, cure, or mitigate diseases, namely, hypercholesteremia, hypertension, and abnormal blood glucose levels. Nothing in your letters changes our view. We do not believe that the claims that were the subject of our letters convey the same meaning as “maintain levels that are already normal” with respect to the meaning the subject claims convey because they do 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 conclusions expressed in our original letters are incorrect and we stand by our original determinations that the claims proposed in your clients’ original submissions are disease claims that subject their products to regulation under the drug provisions of the Act.

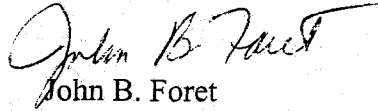
We also stated that we believed several claims regarding blood circulation and coronary blood flow were not appropriate structure/function claims because they implied disease treatment, prevention, or mitigation. We believe that any claim about a product affecting blood flow is an implied disease claim. While blood flow is a normal function of the body, a claim about external intervention to affect blood flow is implicitly a claim to correct a defect in blood circulation because it is not necessary to improve, modify, or otherwise affect blood flow unless it is impaired. However, as discussed above, a claim that a product is important or plays a role in the maintenance or regulation of blood flow that is already normal or that is already within normal limits may be an appropriate structure/function claim, depending on the context.

We also stated that we believed that claims promoting a product for wound healing were disease claims. We do not agree with your assertion that such claims are appropriate structure or function claims. A “wound” fits squarely within the definition of disease in 21 CFR 101.93(g)(1) and any claim that a product is intended to facilitate the healing or treatment of wounds is a disease claim.

Page 3 - Mr. Dennis M. Gronek

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, San Francisco District Office, Compliance Branch, HFR-PA140

Page 4 - 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:6/7/01:docname:75804.adv:disc58

GRONEK & ARMSTRONG

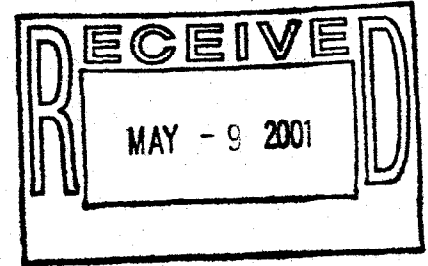
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May 4, 2001



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

Re: Cholesterin Courtesy Letter

Dear Mr. Foret:

This firm represents Horizon Nutraceuticals, Santa Cruz, California. Our client requested that we respond to your March 5, 2001 Courtesy Letter concerning claims made for its Cholesterin product.

In your letter, you object to the claim "...help maintain cholesterol levels within a normal range when consumed as part of a low-cholesterol and low-fat dietary program." We disagree that this claim represents this product for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

In the preamble to the final regulation concerning structure/function claims for dietary supplements (January, 2000), the Food and Drug Administration ("FDA") 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"). The agency also 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 treatment or prevention.

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

In addition, the labeling statement was not made in conjunction with other label statements or representations that imply disease or abnormality. Accordingly, the statement made by our client falls within the universe of acceptable structure/function claims.

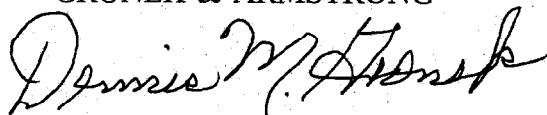
In the preamble, the FDA explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, and that it believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6) 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."

The claim made by Horizon Nutraceuticals in relation to its Cholesterin product is 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 these 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 Horizon Nutraceuticals in relation to its product.

In sum, the statement made in connection with Horizon Nutraceutical's Cholesterin product is entirely consistent with structure/function claims permitted for dietary supplements under DSHEA, 21 CFR §101.93 and public statements by a prominent FDA official.

Please provide us with further information concerning your summary conclusion that "...help maintain cholesterol levels within a normal range when consumed as part of a low-cholesterol and low-fat dietary program" is a disease claim. Until we receive some reasonable explanation that enables use to reconcile your conclusion with the regulation, its preamble and well-publicized comments from prominent FDA officials, we cannot recommend any modification to this label statement.

Sincerely,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

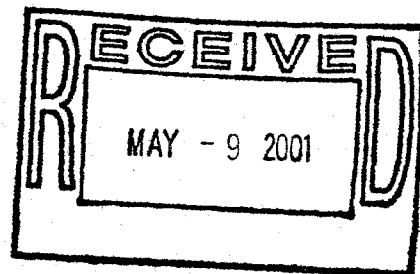
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Center for Food Safety and Applied Nutrition
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Washington, DC 20204

Re: Guggal Cholesterol Compound Courtesy Letter

Dear Mr. Foret:

This firm represents Planetary Formulas, Soquel, California. Our client requested that we respond to your March 7, 2001 Courtesy Letter concerning claims made for its Guggal Cholesterol Compound product.

In your letter, you object to the claim "...help maintain cholesterol levels within a normal range". We disagree that this claim represents this product for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

In the preamble to the final regulation concerning structure/function claims for dietary supplements (January, 2000), the Food and Drug Administration ("FDA") 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"). The agency also 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 treatment or prevention.

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

In addition, the labeling statement was not made in conjunction with other label statements or representations that imply disease or abnormality. Accordingly, the statement made by our client falls within the universe of acceptable structure/function claims.

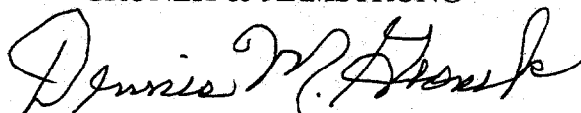
In the preamble, the FDA explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, and that it believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6) 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."

The claim made by Planetary Formulas in relation to its Guggal Cholesterol Compound product is 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 these 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 Source Naturals in relation to its product.

In sum, the statement made in connection with Planetary Formula's Guggal Cholesterol Compound product is entirely consistent with structure/function claims permitted for dietary supplements under DSHEA, 21 CFR §101.93 and public statements by a prominent FDA official.

Please provide us with further information concerning your summary conclusion that "...help maintain cholesterol levels within a normal range" is a disease claim. Until we receive some reasonable explanation that enables use to reconcile your conclusion with the regulation, its preamble and well-publicized comments from prominent FDA officials, we cannot recommend any modification to this label statement.

Sincerely,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

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John B. Foret, Director
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Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Washington, DC 20204

Re: Phytosterol Complex™ Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client requested that we respond to your March 5, 2001 Courtesy Letter concerning claims made for its Phytosterol Complex™ product.

In your letter, you object to the claim "...may help to maintain cholesterol levels within a normal range when consumed with meals as part of a low cholesterol dietary program". We disagree that this claim represents this product for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

In the preamble to the final regulation concerning structure/function claims for dietary supplements (January, 2000), the Food and Drug Administration ("FDA") 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"). The agency also 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 treatment or prevention.

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

In addition, the labeling statement was not made in conjunction with other label statements or representations that imply disease or abnormality. Accordingly, the statement made by our client falls within the universe of acceptable structure/function claims.

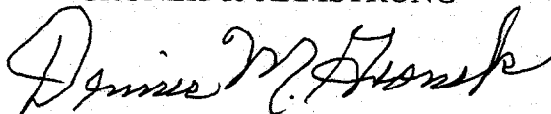
In the preamble, the FDA explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, and that it believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6) 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."

The claim made by Source Naturals in relation to its Phytosterol Complex™ product is 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 these 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 substantially the same claim used by Source Naturals in relation to its product.

In sum, the statement made in connection with Source Natural's Phytosterol Complex™ product is entirely consistent with structure/function claims permitted for dietary supplements under DSHEA, 21 CFR §101.93 and public statements by a prominent FDA official.

Please provide us with further information concerning your summary conclusion that "...may help to maintain cholesterol levels within a normal range when consumed with meals as part of a low cholesterol dietary program" is a disease claim. Until we receive some reasonable explanation that enables use to reconcile your conclusion with the regulation, its preamble and well-publicized comments from prominent FDA officials, we cannot recommend any modification to this label statement.

Sincerely,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

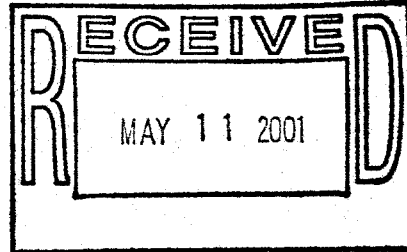
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May 4, 2001



John B. Foret, Director
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U.S. Food and Drug Administration
Washington, DC 20204

Re: Phytosterol Complex™ with 108 mg beta-sitosterol Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client requested that we respond to your Courtesy Letter concerning claims made for its Phytosterol Complex™ with 108 mg beta-sitosterol product.

In your letter, you object to the claim "...may help to maintain normal cholesterol levels when consumed as part of a low cholesterol dietary program". We disagree that this claim represents this product for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

In the preamble to the final regulation concerning structure/function claims for dietary supplements (January, 2000), the Food and Drug Administration ("FDA") 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"). The agency also 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 treatment or prevention.

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

In addition, the labeling statement was not made in conjunction with other label statements or representations that imply disease or abnormality. Accordingly, the statement made by our client falls within the universe of acceptable structure/function claims.

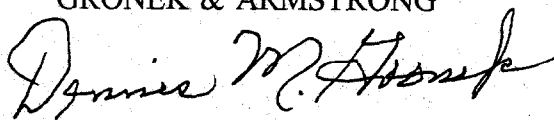
In the preamble, the FDA explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, and that it believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6) 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."

The claim made by Source Naturals in relation to its Phytosterol Complex™ with 108 mg beta-sitosterol product is 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 these 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 substantially the same claim used by Source Naturals in relation to its product.

In sum, the statement made in connection with Source Natural's Phytosterol Complex™ with 108 mg beta-sitosterol product is entirely consistent with structure/function claims permitted for dietary supplements under DSHEA, 21 CFR §101.93 and public statements by a prominent FDA official.

Please provide us with further information concerning your summary conclusion that "...may help to maintain normal cholesterol levels when consumed as part of a low cholesterol dietary program" is a disease claim. Until we receive some reasonable explanation that enables use to reconcile your conclusion with the regulation, its preamble and well-publicized comments from prominent FDA officials, we cannot recommend any modification to this label statement.

Sincerely,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

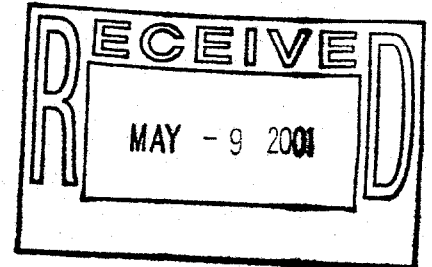
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May 4, 2001



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

Re: Cholestrex Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client requested that we respond to your March 5, 2001 Courtesy Letter concerning claims made for its Cholestrex product.

In your letter, you object to the claim "...may help to maintain healthy cholesterol levels when consumed as part of a low-cholesterol dietary program". We disagree that this claim represents this product for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

In the preamble to the final regulation concerning structure/function claims for dietary supplements (January, 2000), the Food and Drug Administration ("FDA") 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"). The agency also 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 treatment or prevention.

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

In addition, the labeling statement was not made in conjunction with other label statements or representations that imply disease or abnormality. Accordingly, the statement made by our client falls within the universe of acceptable structure/function claims.

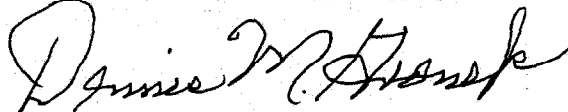
In the preamble, the FDA explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, and that it believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6) 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." Healthy cholesterol levels are "normal".

The claim made by Source Naturals in relation to its Cholestrex product is 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 these 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 substantially the same claim used by Source Naturals in relation to its product.

In sum, the statement made in connection with Source Natural's Cholestrex product is entirely consistent with structure/function claims permitted for dietary supplements under DSHEA, 21 CFR §101.93 and public statements by a prominent FDA official.

Please provide us with further information concerning your summary conclusion that "...may help to maintain healthy cholesterol levels when consumed as part of a low-cholesterol dietary program" is a disease claim. Until we receive some reasonable explanation that enables use to reconcile your conclusion with the regulation, its preamble and well-publicized comments from prominent FDA officials, we cannot recommend any modification to this label statement.

Sincerely,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

ATTORNEYS AT LAW

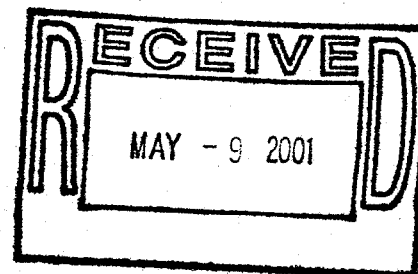
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May 4, 2001



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

Re: Wellness Garlicell™ and Omega EPA™ Courtesy Letters

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client requested that we respond to your March 5, 2001 Courtesy Letter concerning claims made for its Wellness Garlicell™ and Omega EPA™ products.

In your letter, you object to the claim "...to help maintain cholesterol levels within a normal range when taken in conjunction with a low-fat, low-cholesterol diet". We disagree that this claim represents these products for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

In the preamble to the final regulation concerning structure/function claims for dietary supplements (January, 2000), the Food and Drug Administration ("FDA") 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"). The agency also 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 treatment or prevention.

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

In addition, the labeling statement was not made in conjunction with other label statements or representations that imply disease or abnormality. Accordingly, the statement made by our client falls within the universe of acceptable structure/function claims.

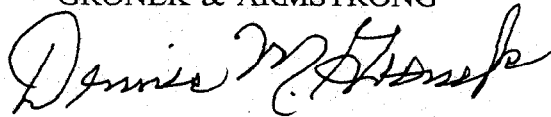
In the preamble, the FDA explicitly stated that it does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims, and that it believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6) 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."

The claim made by Source Naturals in relation to its Garlicell™ and Omega EPA™ products is 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 these 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 Source Naturals in relation to its products.

In sum, the statement made in connection with Source Natural's Garlicell™ and Omega EPA™ products is entirely consistent with structure/function claims permitted for dietary supplements under DSHEA, 21 CFR §101.93 and public statements by a prominent FDA official.

Please provide us with further information concerning your summary conclusion that "...to help maintain cholesterol levels within a normal range when taken in conjunction with a low-fat, low-cholesterol diet" is a disease claim. Until we receive some reasonable explanation that enables use to reconcile your conclusion with the regulation, its preamble and well-publicized comments from prominent FDA officials, we cannot recommend any modification to this label statement.

Sincerely,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

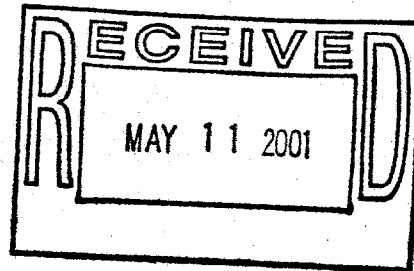
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May 7, 2001



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

Re: Potassium Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client has requested that we respond to your March 7, 2001 Courtesy Letter concerning claims made for its Potassium product.

In your letter, you object to the claim "...regulation of heart action and blood pressure." This is an inaccurate representation of how the claim appears on the label and how the claim was reported to the FDA. In fact, the claim actually reads as follows: "Potassium is essential for...the regulation of heart action and blood pressure." We disagree that this claim represents the product for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

The claim "Potassium is essential for...the regulation of heart action and blood pressure" merely states two of the well established physiological processes in which potassium is involved. There is no reference, direct or implied, on the label or in labeling of the Potassium product which suggests that this product is intended to regulate impaired heart action or high blood pressure. The claim simply states a biological fact and does not mention or suggest treatment or prevention of hypertension or cardiovascular disease or any disease or class of diseases.

Hypertension is that level of blood pressure at which a therapeutic intervention will reduce the risk of subsequent cardiovascular disease. Various criteria for its threshold have been suggested, ranging from 140 mm. Hg systolic and 90 mm. Hg diastolic to as high as

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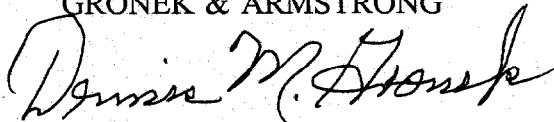
200 mm. Hg systolic and 110 mm. Hg diastolic. Therefore, in order for an individual with elevated blood pressure levels to be considered hypertensive, the levels must be high enough such that therapeutic intervention will reduce the risk of subsequent cardiovascular disease and likely within the range of 140 mm.-200 mm. Hg systolic and 90 mm.-110 mm. Hg diastolic. Individuals with blood pressure below these levels would be considered normotensive.

Blood pressure levels can fluctuate due to various non-disease related external factors, including stress, being overweight and diet and still not reach hypertensive levels. For example, there is a tendency for blood pressure to increase with a high sodium chloride intake even in normotensive individuals. Low calcium intake may amplify the effects of high sodium chloride intake on blood pressure, and calcium supplementation has been reported to decrease the effect of high sodium chloride intake on blood pressure. Also, studies have suggested that societies with high potassium intakes have lower mean blood pressure levels than societies with low potassium intakes not taking into account hypertensive individuals. Therefore, various dietary and non-dietary factors cause blood pressure to increase and decrease without reaching the hypertensive level, and it is normal for blood pressure levels to fluctuate so long as such levels remain below the hypertensive level.

Since the label and labeling for the Potassium product does not represent, explicitly or impliedly, that the product is intended to treat or prevent high blood pressure, hypertension, cardiovascular disease or any disease or class of diseases, we are at a loss as to how the claim "Potassium is essential for...the regulation of heart action and blood pressure" could be interpreted as a disease claim. The claim simply states the physiological fact that potassium plays a role in the regulation of heart action and blood pressure and does not refer to any disease or class of diseases.

Please provide use with further information concerning your position that the statement "Potassium is essential for...the regulation of heart action and blood pressure" is a disease claim.

Sincerely yours,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

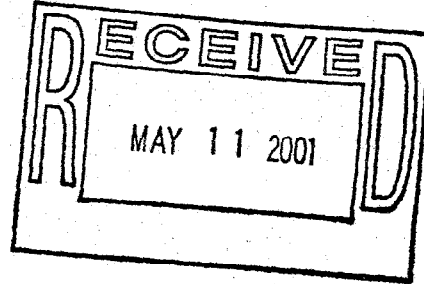
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May 7, 2001



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

Re: Potassium March 7, 2001 Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client has requested that we respond to your Courtesy Letter concerning claims made for its Potassium product.

In your letter, you object to the claim "...regulation of heart action and blood pressure." This is an inaccurate representation of how the claim appears on the label and how the claim was reported to the FDA. In fact, the claim actually reads as follows: "Potassium is essential for...the regulation of heart action and blood pressure." We disagree that this claim represents the product for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

The claim "Potassium is essential for...the regulation of heart action and blood pressure" merely states two of the well established physiological processes in which potassium is involved. There is no reference, direct or implied, on the label or in labeling of the Potassium product which suggests that this product is intended to regulate impaired heart action or high blood pressure. The claim simply states a biological fact and does not mention or suggest treatment or prevention of hypertension or cardiovascular disease or any disease or class of diseases.

Hypertension is that level of blood pressure at which a therapeutic intervention will reduce the risk of subsequent cardiovascular disease. Various criteria for its threshold have been suggested, ranging from 140 mm. Hg systolic and 90 mm. Hg diastolic to as high as

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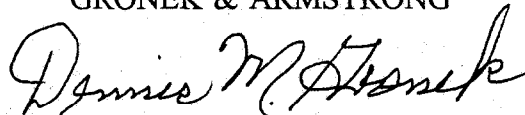
200 mm. Hg systolic and 110 mm. Hg diastolic. Therefore, in order for an individual with elevated blood pressure levels to be considered hypertensive, the levels must be high enough such that therapeutic intervention will reduce the risk of subsequent cardiovascular disease and likely within the range of 140 mm.-200 mm. Hg systolic and 90 mm.-110 mm. Hg diastolic. Individuals with blood pressure below these levels would be considered normotensive.

Blood pressure levels can fluctuate due to various non-disease related external factors, including stress, being overweight and diet and still not reach hypertensive levels. For example, there is a tendency for blood pressure to increase with a high sodium chloride intake even in normotensive individuals. Low calcium intake may amplify the effects of high sodium chloride intake on blood pressure, and calcium supplementation has been reported to decrease the effect of high sodium chloride intake on blood pressure. Also, studies have suggested that societies with high potassium intakes have lower mean blood pressure levels than societies with low potassium intakes not taking into account hypertensive individuals. Therefore, various dietary and non-dietary factors cause blood pressure to increase and decrease without reaching the hypertensive level, and it is normal for blood pressure levels to fluctuate so long as such levels remain below the hypertensive level.

Since the label and labeling for the Potassium product does not represent, explicitly or impliedly, that the product is intended to treat or prevent high blood pressure, hypertension, cardiovascular disease or any disease or class of diseases, we are at a loss as to how the claim "Potassium is essential for...the regulation of heart action and blood pressure" could be interpreted as a disease claim. The claim simply states the physiological fact that potassium plays a role in the regulation of heart action and blood pressure and does not refer to any disease or class of diseases.

Please provide us with further information concerning your position that the statement "Potassium is essential for...the regulation of heart action and blood pressure" is a disease claim.

Sincerely yours,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

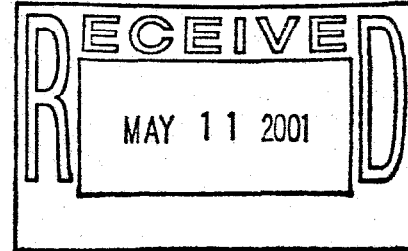
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May 7, 2001



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

Re: HeartResponse and Dura-Carb™ Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client requested that we respond to your February 23, 2001 Courtesy Letter concerning claims made for its HeartResponse and Dura-Carb™ products.

In your letter, you object to the claim "...increase the strength of contraction of the heart and to increase coronary blood flow" made in relation to the HeartResponse product, and the claim "...to support blood sugar regulation" made in relation to the Dura-Carb™ product. We disagree that these claims represent the products for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

The claim "...increase the strength of contraction of the heart and to increase coronary blood flow" made in relation to the HeartResponse product merely describes one of the roles of hawthorn in affecting the structure or function of the body. Neither increasing the strength of heart contractions nor increasing coronary blood flow imply or suggest treatment or prevention of any disease or class of diseases. Nowhere on the label or in labeling of the HeartResponse product is it stated or suggested that hawthorn or the product has any effect on impaired cardiac contractions or blood flow. There is no representation, implied or express, that the product will have any effect in treating or preventing any heart condition, disease or class of diseases.

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In your letter you also object to the claim "...to support blood sugar regulation" made in relation to the Dura-Carb™ product. Blood sugar levels fluctuate throughout the day as a normal and healthy consequence of the digestive process and body fuel regulation. After meals gastrointestinal enzymes hydrolyze carbohydrates and proteins to monosaccharides and amino acids. After absorption, carbohydrates and proteins stimulate insulin secretion. Insulin controls glucose utilization. Insulin stimulates glycogen (chains of glucose residues) synthesis, aerobic and anaerobic glycolysis, protein synthesis and fatty acid syntheses in the liver. After activation by phosphorylation, glucose enters glycogen depots, generates energy in glycolytic and Krebs cycle pathways, and yields precursors for fatty acid and protein synthesis. Other simple sugars enter the glycogen pool, generate energy, or become precursors for synthetic processes. Muscles and adipose tissue receive a large percentage of glucose and amino acids released after large meals. Excess glucose is converted to glycogen and stored in the liver and muscles for use as needed and, beyond that, is converted to fat and stored as adipose tissue.

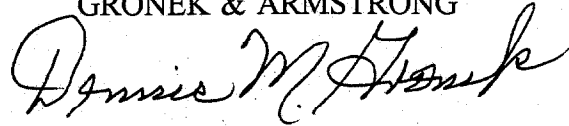
The transition from fed to fasted state is accompanied by a gradual fall in serum insulin and a rise in serum glucagon. The falling ratio of insulin to glucagon slowly switches the liver enzyme machinery from glucose use to glucose production. After 12 or more hours of fasting, half the liver glycogen is depleted. Brain, other nervous tissues, red blood cells, and renal medulla have ongoing requirements of glucose for energy. After long periods of fasting, other tissues can use fatty acids and ketones for energy in the absence of glucose. During short-term fast, serum insulin and glucagon orchestrate changes in fuel homeostasis resulting in a steady supply of glucose to the brain and other glucose-dependent tissues.

Therefore, the simple and natural act of consuming food throughout the day causes fluctuations in blood sugar use, production and storage (fed/fasting states). Dura-Carb™ helps support regulation of the normal and healthy fluctuations in blood sugar use, storage and production by providing a complex carbohydrate load. Complex carbohydrates (versus simple carbohydrates) have a lower glycemic index rating which means that, in general, blood glucose levels do not rise as high or as fast and blood sugar use, production and storage is more steady than it would be if simple carbohydrates were consumed.

There is no representation, express or implied, on the Dura-Carb™ label or in labeling that the product is intended to treat or prevent any disease or class of diseases.

Please provide us with further information concerning your position that "...increase the strength of contraction of the heart and to increase coronary blood flow" and "...to support blood sugar regulation" are disease claims.

Sincerely yours,
GRONEK & ARMSTRONG

A handwritten signature in cursive script, appearing to read "Dennis M. Gronck". The signature is written in dark ink and is positioned below the typed name of the firm.

Dennis M. Gronck

GRONEK & ARMSTRONG

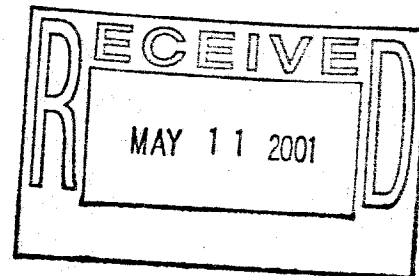
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May, 8 2001



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

Re: Calcium & Magnesium Chelate/Intimate Response™ Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client requested that we respond to your March 5, 2001 Courtesy Letter concerning claims made for its Calcium & Magnesium Chelate and Intimate Response™ products.

In your letter, you object to the claim "...regulation of blood pressure..." made in relation to the Calcium & Magnesium Chelate product, and the claim "...acts on peripheral blood vessels to affect circulation" made in relation to the Intimate Response™ product. In fact, the claims actually read as follows: "Calcium & magnesium...are important in the regulation of blood pressure..." and "Yohimbe...acts on peripheral blood vessels to affect circulation". We disagree that these claims represent the products for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

Claims made on the label and in labeling for the Calcium & Magnesium Chelate product do not represent, explicitly or impliedly, that the product is intended to treat or prevent high blood pressure, hypertension, cardiovascular disease or any other disease or class of diseases. We are at a loss as to how the claim "Calcium and magnesium...are important in the regulation of blood pressure..." could be interpreted as a disease claim. The claim simply states the physiological fact that calcium and magnesium play a role in the regulation of blood pressure and does not refer to any disease or class of diseases.

Hypertension is that level of blood pressure at which a therapeutic intervention will reduce the risk of subsequent cardiovascular disease. Various criteria for its threshold have been suggested, ranging from 140 mm. Hg systolic and 90 mm. Hg diastolic to as high as 200 mm. Hg systolic and 110 mm. Hg diastolic. Therefore, in order for an individual with

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elevated blood pressure levels to be considered hypertensive, the levels must be high enough such that therapeutic intervention will reduce the risk of subsequent cardiovascular disease and likely within the range of 140 mm.-200 mm. Hg systolic and 90 mm.-110 mm. Hg diastolic. Individuals with blood pressure below these levels would be considered normotensive.

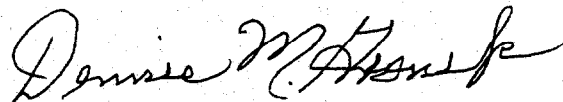
Blood pressure levels can fluctuate due to various non-disease related external factors, including stress, being overweight and diet and still not reach hypertensive levels. For example, there is a tendency for blood pressure to increase with a high sodium chloride intake even in normotensive individuals. Low calcium intake may amplify the effects of high sodium chloride intake on blood pressure, and calcium supplementation has been reported to decrease the effect of high sodium chloride intake on blood pressure. Also, studies have suggested that societies with high potassium intakes have lower mean blood pressure levels than societies with low potassium intakes not taking into account hypertensive individuals. Therefore, various dietary and non-dietary factors cause blood pressure to increase and decrease without reaching the hypertensive level, and it is normal for blood pressure levels to fluctuate so long as such levels remain below the hypertensive level.

A claim that mentions blood pressure and the regulation thereof, without any reference to lowering blood pressure, hypertension, cardiovascular disease or any other disease or class of diseases, is not a disease claim. Blood pressure regulation is a normal and healthy physiological process.

The claim "yohimbe...acts on peripheral blood vessels to affect circulation" merely states a well established physiological process in which yohimbe is involved. There is no reference, direct or implied, on the label or in labeling of the product which suggests that it is intended to treat or prevent diseased blood vessels or poor circulation. The claim simply states a biological fact and does not mention or suggest treatment or prevention of any circulatory disease or class of diseases.

Please provide us with further information concerning your position that the statements "Calcium & magnesium...are important in the regulation of blood pressure..." and "yohimbe...acts on peripheral blood vessels to affect circulation" are disease claims.

Sincerely yours,
GRONEK & ARMSTRONG



Dennis M. Gronek

GRONEK & ARMSTRONG

ATTORNEYS AT LAW

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May, 8 2001

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

Re: OptiZinc®/K-Mag C™ Courtesy Letter

Dear Mr. Foret:

This firm represents Source Naturals, Scotts Valley, California. Our client requested that we respond to your March 5, 2001 Courtesy Letter concerning claims made for its OptiZinc® and K-Mag C™ products.

In your letter, you object to the claim "...healing of wounds..." made in relation to the OptiZinc® product, and the claim "...regulation of heart action and blood pressure..." made in relation to the K-Mag C™ product. In fact, the claims actually read as follows: "Zinc...is essential for...healing of wounds..." and "Potassium is essential for...the regulation of heart action and blood pressure." We disagree that these claims represent the products for the diagnosis, mitigation, treatment, cure or prevention of any disease or class of diseases.

The statement "Zinc...is essential for...healing of wounds..." merely describes one of the universally accepted physiological functions of zinc in the human body. The claim does not state that zinc heals wounds and certainly does not state that the product, OptiZinc® heals wounds. Rather, the claim simply states that zinc, one of the ingredients in the OptiZinc® product, plays a role in the wound healing process. This is a factually accurate statement and does not represent that the product is intended to treat or prevent any disease or class of diseases.

The claim "Potassium is essential for...the regulation of heart action and blood pressure" merely states two of the well established physiological processes in which potassium is involved. There is no reference, direct or implied, on the label or in labeling of the Potassium product which suggests that this product is intended to regulate impaired heart action or high blood pressure. The claim simply states a biological fact and does not mention

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or suggest treatment or prevention of hypertension or cardiovascular disease or any disease or class of diseases.

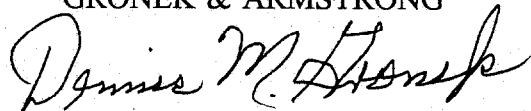
Hypertension is that level of blood pressure at which a therapeutic intervention will reduce the risk of subsequent cardiovascular disease. Various criteria for its threshold have been suggested, ranging from 140 mm. Hg systolic and 90 mm. Hg diastolic to as high as 200 mm. Hg systolic and 110 mm. Hg diastolic. Therefore, in order for an individual with elevated blood pressure levels to be considered hypertensive, the levels must be high enough such that therapeutic intervention will reduce the risk of subsequent cardiovascular disease and likely within the range of 140 mm.-200 mm. Hg systolic and 90 mm.-110 mm. Hg diastolic. Individuals with blood pressure below these levels would be considered normotensive.

Blood pressure levels can fluctuate due to various non-disease related external factors, including stress, being overweight and diet and still not reach hypertensive levels. For example, there is a tendency for blood pressure to increase with a high sodium chloride intake even in normotensive individuals. Low calcium intake may amplify the effects of high sodium chloride intake on blood pressure, and calcium supplementation has been reported to decrease the effect of high sodium chloride intake on blood pressure. Also, studies have suggested that societies with high potassium intakes have lower mean blood pressure levels than societies with low potassium intakes not taking into account hypertensive individuals. Therefore, various dietary and non-dietary factors cause blood pressure to increase and decrease without reaching the hypertensive level, and it is normal for blood pressure levels to fluctuate so long as such levels remain below the hypertensive level.

Since the label and labeling for the Potassium product does not represent, explicitly or impliedly, that the product is intended to treat or prevent high blood pressure, hypertension, cardiovascular disease or any disease or class of diseases, we are at a loss as to how the claim "Potassium is essential for...the regulation of heart action and blood pressure" could be interpreted as a disease claim. The claim simply states the physiological fact that potassium plays a role in the regulation of heart action and blood pressure and does not refer to any disease or class of diseases.

Please provide us with further information concerning your position that the statements "Zinc...is essential for...healing of wounds..." and "Potassium is essential for...the regulation of heart action and blood pressure" are disease claims.

Sincerely yours,
GRONEK & ARMSTRONG



Dennis M. Gronek