DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 16 2001 8523 '01 AUG -8 P2:21

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 June 12 and 15 on behalf of Planetary Formulas, Soquel, California, Source Naturals, Scotts Valley, California, and Horizon Nutraceuticals, Santa Cruz, California. In your letter, you reiterate your disagreement with FDA's view that certain claims that we identified in several letters to the aforementioned firms 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 letters are disease claims is incorrect. Moreover, in our other letters to you, we have provided our explanation about how we reached those conclusions. We believe that the claims that were identified in our letters to the subject firms 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,

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

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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

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June 15, 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

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

Dennis M. Gronek

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June 15, 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: 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

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

Dennis M. Gronek

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June 12, 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 with Ostivone® Courtesy Letter

Dear Mr. Foret:

As previously indicated, this firm represents, Horizon Nutraceuticals, Santa Cruz, California. The following is a response to your May 5, 2001 letter in which you responded to our comments concerning your March 19, 2001 Courtesy Letter objecting to claims made in relation to our client's Calcium with Ostivone® product. We continue to disagree with your position concerning the claim "...help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases."

In your letter you state that the FDA does not believe that the claim "...help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases" is a structure/function claim. As support for this contention you cite to the final regulation concerning structure/function claims (65 FR 1000) which states that the FDA considers the claim "maintain normal bone density in post-menopausal women" to be a disease claim because, according to the FDA, "post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass" (65 FR 1018).

We are perplexed by your citation to 65 FR 1018 because our client is not making the claim cited by the FDA in the preamble to the final structure/function claim regulation. Our client does not claim that its Calcium with Ostivone® product will "maintain normal bone density" or have any affect on bone density or bone mass at all. Our client simply states that its product will "help maintain and support a healthy skeletal system". Maintaining a healthy skeletal system does not imply disease treatment or prevention. The FDA has made clear that it does not intend to preclude structure/function claims that refer to the maintenance of

healthy structure or function, unless they imply disease treatment or prevention (65 FR 1018). Also, the fact that our client's claim includes the statement "...especially during the menopausal years when bone loss increases" does not imply disease treatment or prevention, but rather, simply states the universally accepted physiological fact that women lose bone mass during their menopausal years.

According to the FDA, all persons lose bone with age (21 CFR §101.72; see also, 56 FR 60689). However, not all persons develop the disease state osteoporosis. In fact, the FDA has stated that it believes that the general population is *not* at significant risk of developing osteoporosis (58 FR 2666), and that it is a misconception that the risk of osteoporosis is equally applicable across the general United States population (56 FR 60689). According to the FDA, the most important risk factors for osteoporosis are age, gender, race (Caucasian and Asian) and hormonal status, with post-menopausal Caucasian and Asian women having an increased risk of developing the disease.

Even amongst post-menopausal women, however, the risk of developing osteoporosis is not certain. According to the National Institutes of Health ("NIH"), researchers estimate that only about 23% of American women over the age of 50 have osteoporosis. Therefore, FDA's statement in 65 FR 1018 that "post-menopausal women characteristically develop osteoporosis..." is not true. Also, the FDA acknowledges risk factors for osteoporosis other than age, gender, race and hormonal status, including low dietary calcium, cigarette smoking and alcohol intake (56 FR 60689). Therefore, being a menopausal or post-menopausal woman may increase your risk of developing osteoporosis, however, simply because a woman is menopausal or post-menopausal does not mean she suffers from osteoporosis. Similarly, a statement concerning decreased bone mass with age does not become a disease claim simply because it mentions menopausal or post-menopausal women.

Bone loss with age is normal and happens to everyone, and therefore, some other factor must distinguish the normal state of bone loss with age from the diseased state of osteoporosis. While the FDA maintains that a principal sign of osteoporosis is decreased bone mass, factors other than decreased bone mass are required before the disease of osteoporosis is implicated.

As stated in our April 12, 2001 letter, the FDA has adopted the definition of "osteoporosis" set forth by the NIH as "a disease characterized by low bone mass, where the internal structure of the bone has been eroded to the extent that even slight trauma will cause the bone to fracture easily" (56 FR 60689). "Osteoporosis" means "porous bones" and is a condition of structural deterioration of bone tissue and excessive skeletal fragility resulting in bones that break easily. Therefore, according to the NIH and the FDA, the disease osteoporosis is characterized not only by low or decreasing bone mass (which the FDA explicitly acknowledges as normal with age), but also by a bone structure which is so eroded and porous that even slight trauma will cause the bone to fracture easily. So not only must bone mass be effected for the disease of osteoporosis to exist, but also the structure of the bone tissue must be deteriorated.

Therefore, the claim "...help maintain and support a healthy skeletal system, especially during the menopausal years when bone loss increases" is not a disease claim or an unauthorized health claim. FDA acknowledges that bone loss with age (and menopause) is not a disease and is something that everyone experiences. Only bone loss where the internal structure of the bone has been eroded to the extent that slight trauma will cause the bone to fracture easily is considered a disease. Our client does not make any claim, express or implied, that its Calcium with Ostivone® product will have any effect of bone mass or density or have any effect on the internal structure of the bone or bone tissue.

Your letter does not address any of the arguments set forth in our April 12, 2001 letter. Rather, as a basis for objecting to our client's claim you simply cite to a claim, which we do not make, that the FDA has expressed its objection to. We continue to maintain that the claim is not a disease claim or an unauthorized health claim.

Sincerely,
GRONEK & ARMSTRONG

Dennis M. Gronek

Dennis M. Gronek

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June 12, 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: 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.

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

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June 12, 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.

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

Dennis M. Gronek

GRONEK & ARMSTRONG

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June 12, 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: 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.

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

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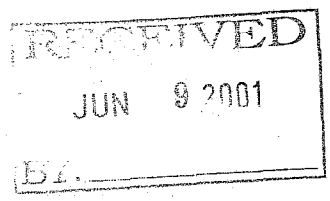
June 12, 2001



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: 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.

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

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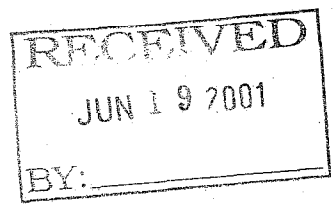
June 12, 2001



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: 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.

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

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June 12, 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.

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

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June 15, 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 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

Dennis M. Gronek