



2759 '03 MAY 28 P2:34

MAY - 8 2003

Ms. Sonia C. Rodriguez
President
Mason Vitamins, Inc.
5105 N.W. 159th Street
Miami Lakes, Florida 33014-6370

Dear Ms. Rodriguez:

This is in response to your letters of March 21, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The products **Vanadyl Sulfate, Cod Liver Oil Softgels, DH Blood Sugar Balance, Garlic Capsules and Softgels, Niacin, Potassium, and Alfalfa Tablets** use the claims "Promotes healthy Blood Sugar Levels...", "Promotes Healthy...Cholesterol...", "Supports Healthy Blood Pressure Levels...", "Promotes Healthy Cholesterol Levels...", "Supports Healthy...Blood Pressure...", and "Supports Healthy Glucose Tolerance..." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), 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 implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about control of blood glucose levels and glucose tolerance and blood pressure; that is, a claim that does not establish that the claims are about blood glucose levels, glucose tolerance, or blood pressure that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes) or elevated blood pressure (hypertension), which are diseases. Therefore, because the claims you are making for the products identified above represent that the products are intended to affect blood pressure and blood cholesterol and glucose levels but do not also include a statement about them being intended to affect blood pressure or blood levels of cholesterol or glucose that are already in the normal range, they are implied disease claims.

The product Echinacea & Goldenseal states that it is to boost immune health "during the Cold Season." The product MSM (Methylsulfonylmethane) uses the claim "Promotes Healthy Allergic Response" and "support healthy allergic responses."

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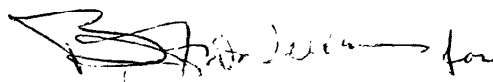
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Page 2 - Ms. Sonia C. Rodriguez

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases such as allergies, the common cold, hypertension, diabetes, and hypercholesterolemia and heart disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

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

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

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

APR 17 2003

March 21, 2003

Office of Special Nutritionals (HF-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

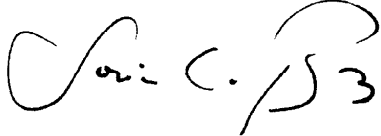
Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Potassium, a dietary supplement.

Statements being made in the labeling of Potassium Capsules

Supports Healthy Blood Pressure Levels & a Healthy Heart

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

MASON VITAMINS, INC.



Sonia C. Rodriguez
President

84143

APR 17 2003

March 21, 2003

Office of Special Nutritionals (HF-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Re: 21 U.S.C. Section 343(r)(6). Notification of Statements on Dietary Supplements

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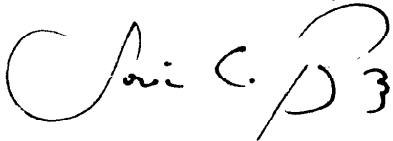
Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Vanadyl Sulfate, a dietary supplement.

Statements being made in the labeling of Vanadyl Sulfate

Promotes Healthy Blood Sugar Levels and Helps Fight Cravings

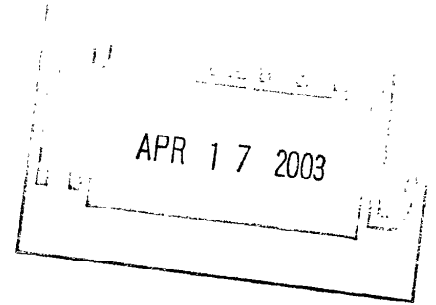
To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

MASON VITAMINS, INC.



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March 21, 2003

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Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Alfalfa Tablets, a dietary supplement.

Statements being made in the labeling of Alfalfa Tablets

Promotes Healthy Joints, Cholesterol, and Energy Levels

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

MASON VITAMINS, INC.

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200 C Street SW
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Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Notice is hereby given the Food and Drug Administraton ("FDA") of the use of statements of nutritional support in the labeling of Niacin, a dietary supplement.

Statements being made in the labeling of Niacin Capsules

Promotes Healthy Cholesterol Levels and Energy Production

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

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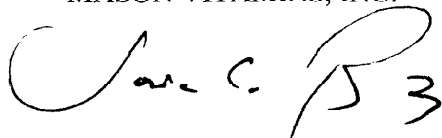
Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Garlic Capsules and Softgels, dietary supplements.

Statements being made in the labeling of Garlic Capsules and Softgels

Promotes Healthy Cholesterol Levels, a Healthy Heart, and Immune System

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

MASON VITAMINS, INC.



Sonia C. Rodriguez
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The Vitamin Marketing Experts

March 21, 2003

Office of Special Nutritionals (HF-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

APR 17 2003

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of DH Blood Sugar Balance, a Dietary supplement.

Statements being made in the labeling of DH Blood Sugar Balance

Supports Healthy Glucose Tolerance and Sugar Metabolism

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

MASON VITAMINS, INC.

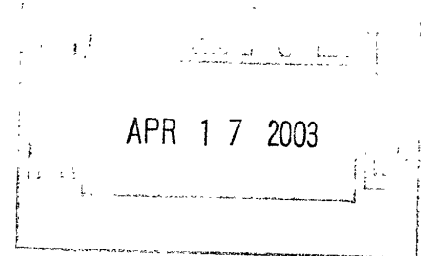
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Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Cod Liver Oil Softgels, a Dietary supplement.

Statements being made in the labeling of Cod Liver Oil Softgels

Supports Healthy Immune System, Blood Pressure, Heart, Brain, Joints, and Skin

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

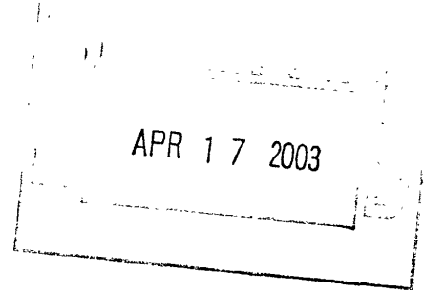
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Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of MSM (Methylsulfonylmethane) 500mg, a dietary supplement.

Statements being made in the labeling of MSM 500mg Capsules

Supports Joint Flexibility and Range of Motion; Essential for Skin, Connective Tissue, Hair and Nails; Promotes Healthy Allergic Response

Evidence has shown that taking daily doses up to 8000mg have been used to promote healthy inflammatory responses. Daily doses of up to 4000mg have been used to support healthy allergic responses.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

MASON VITAMINS, INC.

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Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

Notice is hereby given the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Echinacea & Goldenseal, a dietary supplement.

Statements being made in the labeling of Echinacea & Goldenseal Capsules

Shown to Boost Immune Health, especially during the Cold Season

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Mason Vitamins possesses substantiation that the statements are truthful and not misleading.

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