DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 21 2002

6389 '02 MAR 26 P2:20

Mr. John Morley
President
Natural Factors Nutritional Products, Inc.
1111 80th Street, S.W.
Suite 100
Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letters of November 20, 2001 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)). Your submission states that Natural Factors Nutritional Products, Inc. is making the following claims for the following products:

The product **Chromium & Vanadium** uses the claims "...helps control the blood sugar level and help maintain healthy cholesterol levels" and "helps maintain healthy blood sugar levels." 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 claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol. The same principle applies to your claim about control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

The product **Chromium GTF Chelate** uses the claims "...helps the body maintain a normal blood sugar level," "...helps maintain a health cholesterol level," and "maintains healthy blood sugar levels." For the reasons discussed above, FDA considers the cholesterol claim for your product to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol. Likewise, because your claims about maintaining "normal" or "healthy" blood sugar levels do not make clear that the product is only for people with blood sugar that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

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The product **Betaine Hydrochloride** uses the claims "...helping maintain healthy blood sugar levels" and "maintains blood sugar levels." As discussed above, a claim about maintaining "healthy" blood sugar levels that does not make clear that the product is only for people with blood sugar that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

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. 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, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also stated that you were making the following claims, among others, for the following products:

**Magnesium Oxide**
**Magnesium Chelate**

> "Signs of magnesium deficiency include fatigue, mental confusion, irritability, heart disturbances, muscle cramps, insomnia and a predisposition to stress"
> "For optimal magnesium levels"

**B6 500 mg (Pyridoxine)**
**B6 100 mg (Pyridoxine HCl)**

> "Deficiency of Vitamin B6 is characterized by depression, glucose intolerance, anemia, impaired nerve function, cracking of the lips and tongue, and seborrhea or eczema."

21 U.S.C. 343(r)(6)(A) provides, among other things, that the labeling of a dietary supplement may bear a statement that "claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States." Such a statement may be made if the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, the statement contains the disclaimer statement specified by the statute, the manufacturer submits the required notification no later than 30 days after the first marketing of the dietary supplement, and the statement does not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

The statements that you are making about magnesium and vitamin B6 deficiencies for the products **Magnesium Oxide, Magnesium Chelate, B6 500 mg (Pyridoxine), and B6 100 mg (Pyridoxine HCl)** misbrand these products under 21 U.S.C. 343(r)(6)(A) because they describe a benefit related to a classical nutrient deficiency disease but do not disclose the prevalence of the subject deficiency diseases in the United States. Moreover, some of the statements about these products appear to misbrand the products under 21 U.S.C. 343(a)(1) in that they are false and misleading because they list deficiency symptoms not typically associated with deficiencies of vitamin B6 (i.e., glucose intolerance) or magnesium (insomnia).

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. 21 U.S.C. 321(g)(1) (last sentence) provides that a food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) (i.e., 21 U.S.C. 321(g)(1)(C)) solely because the label or the labeling contains such a statement. In that the statements being made for the products **Magnesium Oxide, Magnesium Chelate, B6 500 mg (Pyridoxine), and B6 100 mg (Pyridoxine HCl** are not made in accordance with 21 U.S.C. 343(r)(6), they suggest that the products are intended to treat, prevent, mitigate, or cure diseases or are articles (other than food) intended to affect the structure or any function of the body of man. 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 (C), and that they are subject to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely,

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

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340

# Natural Factors Nutritional Products Inc.

RECEIVED
JAN - 7 2002

November 20, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

| | |
|---|---|
| Supplement: | Chromium & Vanadium |
| Manufacturer, packer: | Natural Factors Nutritional Products, Ltd.<br>1550 United Blvd.<br>Coquitlam, B.C.<br>Canada V3K 6Y7 |
| Distributor: | Natural Factors Nutritional Products, Inc.<br>1111 80th St. SW, Suite 100<br>Everett, WA 98203 |
| Text of side Panel: | Natural Factors Chromium and Vanadium help control the blood sugar level and help maintain healthy cholesterol levels.* |
| Text of PDP: | HELPS MAINTAIN HEALTHY BLOOD SUGAR LEVELS* |

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

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November 20, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

| | |
|---|---|
| Supplement: | Chromium GTF Chelate |
| Manufacturer, packer: | Natural Factors Nutritional Products, Ltd.<br>1550 United Blvd.<br>Coquitlam, B.C.<br>Canada V3K 6Y7 |
| Distributor: | Natural Factors Nutritional Products, Inc.<br>1111 80th St. SW, Suite 100<br>Everett, WA 98203 |
| Text of side Panel: | Chromium is an essential mineral that helps the body maintain a normal blood sugar level. This is accomplished by Chromium's special GTF (Glucose Tolerance Factor) quality. Chromium also helps maintain a healthy cholesterol level.* Natural Factors Chromium GTF is in the bioavailable form of a chelate to meet your needs. |
| Text of PDP: | MAINTAINS HEALTHY BLOOD SUGAR LEVELS* |

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

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200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

| | |
|---|---|
| Supplement: | Betaine Hydrochloride |
| Manufacturer, packer: | Natural Factors Nutritional Products, Ltd.<br>1550 United Blvd.<br>Coquitlam, B.C.<br>Canada V3K 6Y7 |
| Distributor: | Natural Factors Nutritional Products, Inc.<br>1111 80th St. SW, Suite 100<br>Everett, WA 98203 |
| Text of side Panel: | Betaine Hydrochloride creates a favorable digestive environment in the stomach by providing a supplemental source of hydrochloric acid. Fenugreek also aids digestion while helping maintain healthy blood sugar levels.* |
| Text of PDP: | ENHANCES NORMAL DIGESTION AND MAINTAINS BLOOD SUGAR LEVELS* |

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

[redacted]

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Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

| | |
|---|---|
| Supplement: | Magnesium Oxide |
| Manufacturer, packer: | Natural Factors Nutritional Products, Ltd.<br>1550 United Blvd.<br>Coquitlam, B.C.<br>Canada V3K 6Y7 |
| Distributor: | Natural Factors Nutritional Products, Inc.<br>1111 80th St. SW, Suite 100<br>Everett, WA 98203 |
| Text of side Panel: | Magnesium is an important mineral that functions primarily in the activation of cellular enzymes.* Signs of magnesium deficiency include fatigue, mental confusion, irritability, heart disturbances, muscle cramps, insomnia and a predisposition to stress. |
| Text of PDP: | FOR OPTIMAL MAGNESIUM LEVELS |

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

[redacted]

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Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

| | |
|---|---|
| Supplement: | Magnesium Chelate |
| Manufacturer, packer: | Natural Factors Nutritional Products, Ltd.<br>1550 United Blvd.<br>Coquitlam, B.C.<br>Canada V3K 6Y7 |
| Distributor: | Natural Factors Nutritional Products, Inc.<br>1111 80th St. SW, Suite 100<br>Everett, WA 98203 |
| Text of side Panel: | Magnesium is an important mineral that functions primarily in the activation of cellular enzymes.* Signs of magnesium deficiency include fatigue, mental confusion, irritability, heart disturbances, muscle cramps, insomnia and a predisposition to stress. |
| Text of PDP: | FOR OPTIMAL MAGNESIUM LEVELS |

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

[redacted]

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# Natural Factors Nutritional Products Inc.

2002

November 15, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

| | |
|---|---|
| Supplement: | B6 500mg (Pyridoxine) |
| Manufacturer, packer: | Natural Factors Nutritional Products, Ltd.<br>1550 United Blvd.<br>Coquitlam, B.C.<br>Canada V3K 6Y7 |
| Distributor: | Natural Factors Nutritional Products, Inc.<br>1111 80th St. SW, Suite 100<br>Everett, WA 98203 |
| Text of side Panel: | Vitamin B6 (Pyridoxine) is involved in the formation of body proteins and structural compounds including chemical transmitters in the brain. Vitamin B6 is also critical in maintaining hormonal balance and proper immune function.* Deficiency of Vitamin B6 is characterized by depression, glucose intolerance, anemia, impaired nerve function, cracking of the lips and tongue, and seborrhea or eczema. |
| Text of PDP: | TIME RELEASED |

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

[redacted]

78845

# Natural Factors Nutritional Products Inc.

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JAN - 7 2002

November 15, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

| | |
|---|---|
| Supplement: | B6 100mg (Pyridoxine HCl) |
| Manufacturer, packer: | Natural Factors Nutritional Products, Ltd.<br>1550 United Blvd.<br>Coquitlam, B.C.<br>Canada V3K 6Y7 |
| Distributor: | Natural Factors Nutritional Products, Inc.<br>1111 80th St. SW, Suite 100<br>Everett, WA 98203 |
| Text of side Panel: | Vitamin B6 (Pyridoxine) is involved in the formation of body proteins and structural compounds including chemical transmitters in the brain. Vitamin B6 is also critical in maintaining hormonal balance and proper immune function.* Deficiency of Vitamin B6 is characterized by depression, glucose intolerance, anemia, impaired nerve function, cracking of the lips and tongue, and seborrhea or eczema. |
| Text of PDP: | SUPPORT FOR NERVES, STRESS & IMMUNE SYSTEM* |

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