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MAR 23 2006

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 letter of February 28, 2006 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)).

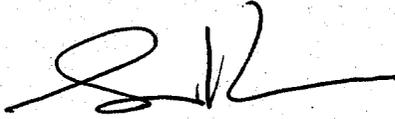
The product **Cholesterol Formula with Sytrinol™** is using the claims "Diets low in saturated fat and cholesterol that include Sytrinol™ Cholesterol Formula consumed with at least two meals may lower cholesterol levels and reduce the risk of heart disease" and "Helps maintain healthy cholesterol levels." These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B) because they represent that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has authorized a health claim about the relationship between phytosterol and phytostanol esters and coronary heart disease (see 21 CFR 101.83)¹. A dietary supplement that meets the eligibility and message requirements set forth in the regulation may bear a claim for the relationship between phytosterol/stanol esters and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.83 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.83 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

¹Also see February 14, 2003 letter regarding enforcement discretion with respect to expanded use of an interim health claim rule about plant sterol/stanol esters and reduced risk of coronary heart disease; <http://www.cfsan.fda.gov/~dms/ds-ltr30.html>.

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Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
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-310
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

February 28, 2006

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FEB 14 2006

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C Street 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: Cholesterol Formula with Sytrinol™

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Place
Burnaby, B.C.
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th Street SW, Suite 100
Everett, WA 98203

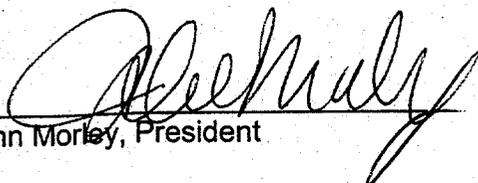
Text of Side Panel: Diets low in saturated fat and cholesterol that include Sytrinol™ Cholesterol Formula consumed with at least two meals may lower cholesterol levels and reduce the risk of heart disease.

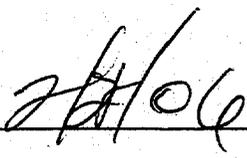
Text on PDP: Helps maintain healthy cholesterol levels.

Name of dietary ingredient that is the subject of statement: SterolSource™, Sytrinol™ Phytosterol.

Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President


Date

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