



8375 '02 APR 12 P1:35

APR - 9 2002

Ms. Maria Solomon
Legal Assistant
Natrol, Inc.
21411 Prairie Street
Chatsworth, California 91311

Dear Ms. Solomon:

This is in response to your letter of March 22, 2002 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)). In your letter, you notified us about a claim you intend to use for your dietary supplement **Laxativ-a-Tea**.

The product **Laxativ-a-Tea** uses the claim "...regain your regularity..." and "...deliver gentle relief...". In the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1026 and 1031), FDA stated that claims that a product was a laxative or that it was intended to treat constipation did not necessarily constitute implied disease claims. We stated, however, that claims that a product is a laxative or that it was intended to treat constipation were disease claims unless the context of the claim makes clear that the product is only for occasional irregularity or occasional constipation. This is because an unqualified claim that a product is a laxative, or is intended to treat constipation implies that the product is intended to treat chronic constipation, a disease, as well as occasional constipation or irregularity, conditions that are not diseases or characteristic symptoms of a disease. The claim for your product contains no context that makes clear it is not intended to treat chronic constipation and it is, therefore, an implied disease claim.

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 statement that you are making for this product, including the name of the product, suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

975-0163

LET 583

Page 2 - Ms. Maria Solomon

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, Los Angeles District Office, Office of Compliance, HFR-PA240

March 22, 2002

UPS 1Z 29E W58 37 1000 766 2
and Regular Mail

Office of Special Nutritionals, HFS-450
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street SW.
Washington, District of Columbia 20204

79926

RECEIVED
APR 01 2002
BY:

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

Dear Sir or Madam:

On behalf of Natrol, Inc., I hereby notify the Food and Drug Administration of the use of statements of nutritional support for the following dietary supplement products:

- | | |
|-----------------|---|
| Acidophilus | By taking Acidophilus each day, you can maintain nutritional balance, environmental factors, and the stress of day-to-day life by:
Maintaining a healthy balance of "friendly" bacteria on your digestive system.
Supports digestive health & function. Helps with lactose intolerance. Promotes Digestive Health |
| B-100 Complex | Stress Support |
| Beta Sitosterol | Beta Sitosterol, also known as Phytosterols, have shown efficacy in maintaining cholesterol levels that are already within a normal range when combined with a low fat diet and regular exercise. |
| Borage Oil | Promotes Cardiovascular health by incorporating the "good fats" found in Borage Oil.
Supports Cardiovascular Health |
| CoEnzyme Q-10 | Promotes Energy Production in Heart |
| Fat Intercept | Taken one minute before meals, Fat Intercept Plus goes to work to prevent absorption of up to several times it's weight in fat.
The Ultimate Fat Blocker |
| GINKGO BILOBA | This ensures that you benefit from the many health-promoting properties such as improved circulation, sexual function and maximized mental focus and clarity. |
| GoldenSeal | Immune Support |

www.natrol.com

Hot Flashex	Vitamin E and Calcium to meet the changing nutritional needs of women throughout all stages of life. Provides: Black Cohosh for hormonal support Vitamin E to provide antioxidants. Chamomile to help calm and relieve stress.
Omega-3	Increasing research reveals the health-promoting properties of Omega-3 fatty acids- EPA and DHA- in supporting a healthy cardiovascular system. Promotes Cardiovascular Health.
PC Care	Through several metabolic pathways this product is designed to provide key support for optimal prostate health. Advanced Prostate Health
SelenoExcell	Selenium is an essential mineral which provides potent antioxidant activity. Maintain Healthy Colon, Lung & Prostate Functions
Siberian Ginseng	Siberian Ginseng enhances physical and mental resistance to environmental stress, while fortifying general endurance. More Energy
Vitamin E	Natural Vitamin E preserves the integrity of cellular membranes throughout the body by scavenging free radicals that break down membrane lipids. Antioxidant Protection for Heart and Brain.
Alpha Lipoic Acid	Alpha Lipoic Acid is a powerful antioxidant. Natrol's Alpha Lipoic Acid helps protect the body from exercise and age related oxidative damage. Another amazing property of Alpha Lipoic Acid supplementation is it's unique ability to support glucose uptake by cells. Antioxidant Support
The Ultimate AntiOxidant Formula	The Ultimate AntiOxidant Formula
Effervescent Calcium plus Vitamin D	Also included in this formula is Vitamin D to assist in the absorption of calcium. For Superior Bone Health
Carb Intercept	Carb Intercept is a highly effective carbohydrate inhibitor, preventing carbs from breaking down, converting to glucose, and being stored as fat. Works by "intercepting" digestive enzyme Alpha-Amylase and Alpha-Glucosidase. Intercepting these enzymes prevents carbohydrates, including table sugar, from being metabolized and possibly converting to fat. Each two capsules may "intercept" 35 – 45 calories per meal. First weight loss supplement with sugar blocking ingredient Inosine. The Ultimate Carb Blocker
CitriMax Plus with ChromeMate	Natrol's CitriMax Plus offers a unique combination formula to support weight management. Weight Management

Natrol Complete Balance	Natrol Complete Balance PM Formula helps reduce night sweats and assists in getting a good nights rest. Natrol Complete Balance AM Formula helps alleviate hot flashes and provides mood support.
DHA Neuromins	This distinct Omega-3 Fatty Acid is vital for fetal development and cerebral functioning. Brain Support
Digest Support	Helps maintain a healthy digestive tract.
Dry Mouth Relief	Enhances and helps promote normal salivary function Promotes oral comfort
Echinacea Goldenseal	Immune Support
Ester-C Effervescent	Can help meet your daily needs of Vitamin C. Contains metabolites that may enhance the delivery of essential Vitamin C to the cells of the body.
Ester-C Boost	Vitamin C is a key antioxidant to fight free radical stress. Vitamin B12 is an essential nutrient involved in the metabolism of energy producing carbohydrates & fatty acids.
Fiberlicious	Promotes Regularity Helps maintain cholesterol levels that are already within normal range.
5-HTP	Natrol's 5-HTP works naturally by increasing your body's own serotonin levels which play a key role in controlling appetite and enhancing mood. Natrol's 5-HTP will help you control your weight while maintaining a positive, healthy outlook. Promotes Balanced Serotonin Levels
Flax Seed Oil	Supports Cardiovascular Health Heart Health
Folic Acid	Folic Acid is a critical nutrient for women of childbearing years. Folic Acid is also an essential vitamin important in maintaining heart health & fetal development.
Ginger Root	Helps support the stomach & digestive system.
Glucosamine Chondroitin & MSM	Natrol has combined three of the best Joint Health ingredients to give your joints a rest. First, Glucosamine has been shown to repair and regenerate cartilage tissue. Second, Chondroitin helps promote lubricating fluids for your joints and cartilage. Third, our patented MSM helps maintain elasticity of joint tissues. 1...2...3...useful ingredients for promoting flexibility, mobility, and of course, comfort. Supports Joint Flexibility and Comfort

- Laxativ-a-Tea** Laxativ-a-Tea helps you regain your regularity in a relaxing and flavorful way. The active ingredient in Laxativ-a-Tea is Senna, a well known herb used to deliver gentle relief and support the body's regular bowel function for hundreds of years in traditional Asian and European herbal medicines.
- Memory Complex** Natrol's Memory Complex is a unique formulation designed to provide the most cutting edge nutrients to help maximize brain function. This scientific brain support formula includes important compounds such as Phosphatidyl Serine, key to neural support communication. Central to the power of this formula is Vinpocetine, from the periwinkle plant, and Huperzine-A, herbal extracts that help to maintain overall mental capacity and neural support. Ginkgo Biloba is added to support energy levels and maximum circulation.
Memory Complex
Formulated to Assist Mild Memory Problems Associated with Aging.
- MetaboFirm** MetaboFirm is formulated to create a thermogenic response which in turn raises energy levels and speeds up metabolism. Along with an appropriate diet and exercise, MetaboFirm may help you achieve your weight loss goals.
Enhance Your Diet and Provide Energy
- Skin-Hair-Nails** A Strengthening & Nourishing Formula
- XetaSlim** XetaSlim is formulated to create a thermogenic response which in turn raises energy levels and speeds up metabolism. Along with an appropriate diet and exercise, XetaSlim may help you achieve your weight loss goals.

Please be advised that the label of each of the above dietary supplement products includes the statement that "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease."

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. Natrol, Inc. possesses substantiation that the statements are truthful and not misleading.

Sincerely,

NATROL, INC.



Maria Solomon
Legal Assistant

MS/abs
FDA-004

cc: Elliott Balbert, President/CEO
Laura Moore, Corporate Secretary