

PHARMATON
NATURAL HEALTH PRODUCTS

Thomas W. Peterson

March 13, 1997

VIA HAND DELIVERY

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

0050 '97 SEP 19 P1:32

RE: VITASANA™ Gelcaps

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products, Division of Boehringer Ingelheim Pharmaceuticals, Inc., wishes to notify the Food and Drug Administration that within the past 30 days the company has begun marketing a dietary supplement with a label which bears statements of nutritional support.

The dietary supplement for which the statements are made is VITASANA™ Gelcaps, which consist of Standardized Ginseng Extract G115® and essential vitamins and minerals. The statements of nutritional support read as follows:

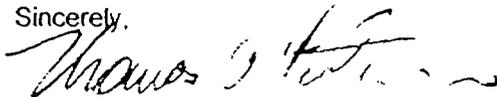
"Promotes Vitality and Well-Being"

"Vitality Promoting"

A copy of the package and container label for each size (60 and 90 Gelcaps) of the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. (The disclaimer is in bold print in a box.) The Company possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under the DSHEA.

Sincerely,



Thomas W. Peterson

Enclosures

97S-0162

LET 561

▲ Promotes Vitality & Well-Being
 ▲ Scientifically Blended Formula
 of G115® Ginseng, Essential
 Vitamins & Minerals
 Easy to Swallow Gelcaps



90

DIETARY SUPPLEMENT

Vitasana
 MULTIVITAMIN, MINERALS & G115® GINSENG

Ginsana®

Ginsana®

MULTIVITAMIN, MINERALS & G115® GINSENG

Vitasana

DAILY DIETARY SUPPLEMENT

90 Easy to Swallow Gelcaps



PROMOTES VITALITY & WELL-BEING FOR A LIFETIME
 Scientifically balanced formula of standardized G115®
 ginseng extract, essential vitamins & minerals

Vitasana
 MULTIVITAMIN, MINERALS & G115® GINSENG

Vitasana
 MULTIVITAMIN, MINERALS & G115® GINSENG

NEW

NEW

Vitasana™

PROMOTES VITALITY & WELL-BEING FOR A LIFETIME
Scientifically balanced formula of standardized G115®
ginseng extract, essential vitamins & minerals

MULTIVITAMIN, MINERALS & G115® GINSENG
Vitasana™

Ginsana®

MULTIVITAMIN, MINERALS & G115® GINSENG
Vitasana™

- DIETARY SUPPLEMENT**
- ▲ Promotes Vitality & Well-Being
 - ▲ Scientifically Blended Formula of G115® Ginseng, Essential Vitamins & Minerals

THIS PACKAGE
FOR HOUSEHOLDS
WITHOUT YOUNG
CHILDREN



60
Easy to Swallow Gelcaps

Ginsana®

MULTIVITAMIN, MINERALS & G115® GINSENG

Vitasana™

DAILY DIETARY SUPPLEMENT

60 Easy to Swallow Gelcaps



Recommended Adult Intake: Adults over 12 years old should take two gelcaps in the morning and one in the afternoon. Optimal effectiveness after 4 weeks of continuous use.

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

VITASANA is a trademark of Pharmaton Natural Health Products, Division of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06477. Distributed by:

PHARMATON
NATURAL HEALTH PRODUCTS

Ridgefield, CT 06477

Product of Canada

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BA3180

Warning: Close tightly and keep out of reach of children. Contains iron, which can be harmful or fatal to children in large doses. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. Store at room temperature and avoid excessive heat above 40°C (104°F) to maintain optimal freshness.

Do not use this product if the safety seal under the cap is torn or missing. **LOT#09 55020CA/01**

The statements presented on this package have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Ginsana
Vitasana
MULTI-VITAMIN SUPPLEMENT

- ▲ Promotes Vitality & Well-Being
- ▲ Scientifically Blended Formula of G115® Ginseng, Essential Vitamins & Minerals

60 Easy to Swallow Gelcaps

Each Serving Contains	% Daily Value
Vitamin A 4000 IU (as beta carotene)	80%
Vitamin C 180 mg (as ascorbic acid)	360%
Vitamin D 400 IU (as cholecalciferol)	100%
Vitamin E 30 IU (as d-alpha-tocopheryl acetate)	100%
Vitamin B1 2 mg (as thiamine mononitrate)	100%
Vitamin B2 3 mg (as riboflavin)	200%
Vitamin B3 30 mg (as niacinamide)	200%
Vitamin B6 4 mg (as pyridoxine HCl)	200%
Folic Acid 400 mcg	100%
Vitamin B12 2 mcg (as cyanocobalamin)	100%
Calcium 200 mg (as calcium phosphate)	33%
Iron 18 mg (as ferrous sulfate)	100%
Phosphorus 180 mg (as calcium phosphate)	100%
Magnesium 30 mg (as magnesium oxide)	15%
Zinc 5 mg (as zinc sulfate)	5%
Copper 2 mg (as copper sulfate)	100%
Manganese 2 mg (as manganese sulfate)	100%
Potassium 5 mg (as potassium chloride)	100%

Other ingredients: Microcrystalline Cellulose, Gelatin, Malic Acid Syrup, Powdered, Glycerin, Croscarmellose Sodium, Magnesium Stearate, Colloidal Silica, Hydroxypropyl Methylcellulose, Ethylcellulose, Titanium Dioxide, Dibutyl Sebacate, Stearic Acid, FD&C Yellow Lake/10, Polysorbate 80, FD&C Blue Lake/1, Vanillin Powder, Polyethylene Glycol, FD&C Yellow Lake/6, EDTA Disodium.