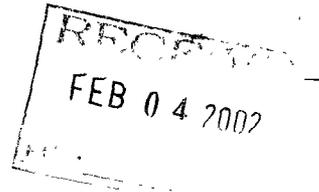


January 29, 2002

Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204



**Re: Notification of Statements for VistaVitamins™ Wellness Plus Formula Dietary Supplement**

Dear Sirs/Madame;

Pursuant to 21 CFR 101.93 (a) (1), Vista Medical Technologies hereby submits three copies of this notification for the statements of nutritional support for the dietary supplement marketed as VistaVitamins™ Wellness Plus. Vista Medical Technologies believes these statements represent permitted structure/function statements as defined in 21 CFR Section 101.93 (f).

Attached to this notification are the Supplement Facts listed on the product labeling.

**Required Information**

**Name and Address of Distributor:**

Vista Medical Technologies  
5451 Avenida Encinas, Suite A  
Carlsbad, CA 92009-4413

**Text of Statement(s) being Made:**

“Scientifically formulated to meet the specific essential vitamin and mineral requirements of the Gastric Bypass Surgery Patient”;

“Specifically formulated to meet the unique nutritional requirements of the Gastric Bypass Patient.

- Replenish your system and optimize your absorption of vital micronutrients.
- Easy-to-take capsules, in daily dosage packets, contain optimal levels of essential vitamins and minerals”;

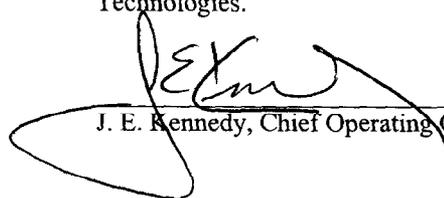
“Help your body get the nutrients it needs to maintain your health”.

**Name of Dietary Supplement:**

VistaVitamins™ Wellness Plus Formula

**Certification:**

I certify that the information contained in this notice is complete and accurate and substantiation that these statements are truthful and not misleading are on file at Vista Medical Technologies.

  
\_\_\_\_\_  
J. E. Kennedy, Chief Operating Officer

1-29-02  
Date

**Vista Medical Technologies**

134 Flanders Road  
Westborough, MA 01581

Ph 508 366-8882  
Fx 508 366-8858

97S 0162

LET 9391

Page 2 of 2

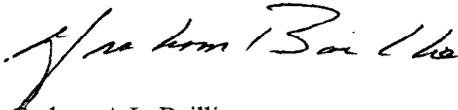
January 29, 2002

Notification of Statements for VistaVitamins™ Wellness Plus Formula Dietary Supplement

Vista Medical Technologies believes that the **VistaVitamins** dietary supplements are exempt from Section 201 (g) (1) (C) of The Federal Food, Drug, and Cosmetic Act (the Act) by compliance with Section 403 (r) (6) of the Act. The following disclaimer statement text (per 21 CFR 101.93 (a) (3) (2)) appears on the product labeling where ever the above statements appear in the labeling: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease".

If you have any questions about this notification, please contact me at (508) 366-3668, extension 8279.

Sincerely,



Graham A.L. Baillie  
Manager, Quality Assurance and Service

Attachment: Supplement Facts from product labeling

# VistaVitamins Wellness Plus

## Supplement Facts

Serving Size: 1 Packet

Servings Per Container: 14

Amount Per Serving	AM Packet		PM Packet	
		% Daily Value		% Daily Value
Vitamin A (as retinyl palmitate)	5000 IU	100%	5000 IU	100%
Vitamin A (as alpha and beta carotene)**	2500 IU	*	2500 IU	*
Vitamin C (as ascorbic acid)	120 mg	200%	120 mg	200%
Vitamin D (as cholecalciferol)	400 IU	100%	400 IU	100%
Vitamin E (as d-alpha tocopheryl succinate)	50 IU	167%	50 IU	167%
Vitamin K (as phylloquinone)	60 mcg	75%	60 mcg	75%
Thiamin (as thiamin hydrochloride)	12 mg	800%	12 mg	800%
Riboflavin	13 mg	765%	13 mg	765%
Niacin (as niacinamide)	16 mg	80%	16 mg	80%
Vitamin B6 (as pyridoxine hydrochloride)	14 mg	700%	14 mg	700%
Folic Acid	400 mcg	100%	400 mcg	100%
Vitamin B12 (as methylcobalamin)	120 mcg	2000%	120 mcg	2000%
Biotin	150 mcg	50%	150 mcg	50%
Pantothenic Acid (as d-calcium pantothenate)	10 mg	100%	10 mg	100%
Calcium (as calcium amino acid chelate)††	150 mg	15%	150 mg	15%
Iron (as Ferrochel® ferrous bis-glycinate)††	4 mg	22%	4 mg	22%
Iodine (as potassium iodide)	75 mcg	50%	75 mcg	50%
Magnesium (as magnesium amino acid chelate)††	100 mg	25%	100 mg	25%
Zinc (as Chelazome® amino acid chelate)††	11 mg	73%	11 mg	73%
Selenium (as selenium amino acid complex)†	70 mcg	100%	70 mcg	100%
Copper (as Chelazome® amino acid chelate)††	0.45 mg	23%	0.45 mg	23%
Manganese (as Chelazome® amino acid chelate)††	1.15 mg	58%	1.15 mg	58%
Chromium (as Chelavite® amino acid chelate)††	75 mcg	63%	75 mcg	63%
Molybdenum (as molybdenum amino acid chelate)††	22.5 mcg	30%	22.5 mcg	30%
Potassium (as potassium chloride)	49.5 mg	< 2%	49.5 mg	< 2%
Boron (as boron amino acid complex)†	0.75 mg	*	0.75 mg	*
Arabinogalactans (Larix occidentalis)	250 mg	*	250 mg	*
Lactobacillus sporogenes	5 million	*	5 million	*

\*Daily Value not established.

\*\*Natural mixed carotenoids, alpha, beta, gamma carotenes, lycopene, beta cryptoxanthin, lutein, and zeaxanthin.

**Other Ingredients:** Gelatin, cellulose, stearic acid, silicon dioxide, magnesium stearate and titanium dioxide.

Chelazome, Chelavite, Ferrochel and the Gold Medallion design are registered trademarks of Albion Laboratories, Inc.

†Albion Advanced Nutrition Amino Acid Complex

††Covered by Albion International, Inc., U.S. Patents 4,599,152 4,830,716 4,863,898 and 5,614,553.