



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 VistaVitaminsTM Chewable Wellness Formula Dietary Supplement

Dear Sirs/Madame;

Pursuant to 21 CRF 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 VistaVitaminsTM Chewable Wellness Formula Dietary Supplement. Vista Medical Technologies believes these statements represent permitted structure/function statements as defined in 21 CRF 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:

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

"Replenish your system and optimize your absorption of vital micronutrients."

"Designed to meet the needs of the pre and immediate postoperative gastric bypass surgery patient."

"The chewable wafers are great tasting, easy to digest, and easy to absorb."

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

Name of Dietary Supplement:

VistaVitamins™ Chewable Wellness 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.

ennedy, Chief Operating Officer

Vista Medical Technologies

134 Flanders Road Westborough MA 01581

7-3-2002.

Ph 508 366-3668 Ex 508 366-1543

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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 8273.

Sincerely

Christine Nichols, RAC Regulatory Affairs

Vista Medical Technologies

Attachment: Supplement Facts from product labeling

VistaVitamins

Chewable Wellness Formula

Supplement Facts

Serving Size: 5 chewables wafers

Vitamın A (as retinyl palmitate) Vitamın A (as beta carotene)	10000 IU	
Vitamın A (as beta carotene)	1000010	200%
	5000 IU	*
Vitamin C (as ascorbic acid)	200 mg	333%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopheryl succinate)	100 IU	333%
Thiamin (as thiamin hydrochloride)	10 mg	667%
Riboflavin	10 mg	588%
Niacin (as niacinamide)	32 mg	160%
Vitamın B6 (as pyridoxine hydrochloride)	10 mg	500%
Folic Acid	800 mcg	200%
Vitamın B12 (as methylcobalamin)	150 mcg	2500%
Biotin	300 mcg	100%
Pantothenic Acid (as d-calcium pantothenate)	20 mg	200%
Calcium (as buffered amino acid chelate)†	300 mg	30%
Iron (as ferrous bis-glycinate)†	18 mg	100%
lodine (as potassium iodide)	150 mcg	100%
Magnesium (as buffered amino acid chelate)†	200 mg	50%
Zinc (as amino acid chletate)†	15 mg	100%
Selenium (as amino acid complex)†	50 mcg	71%
Copper (as amino acid chelate)†	0.90 mg	45%
Manganese (as amino acid chelate)†	2 mg	100%
Chromium (as amino acid chelate)†	100 mcg	83%
Molybdenum (as amino acid chelate)†	45 mcg	60%
Potassium (as potassium chloride)	99 mg	2%
Boron (as amino acid complex)†	1.5 mg	*

Other Ingredients: Xylitol, sorbitol powder, citric acid, stearic acid, citrus punch flavor, ethocel, silicon dioxide, stevia and magnesium stearate.

†All amino acid chelates and complexes supplied by Albion Advanced Nutrition, under the tradenames Albical®, Chelavite®, Chelazome®, and Ferrochel®, and covered by Albion International, Inc. U.S. Patents 4,830,716, 4,863,898, and 5,614,553. Albical, Chelavite, Chelazome, Ferrochel, and the Albion Medallion design are registered trademarks of Albion Laboratories, Inc.