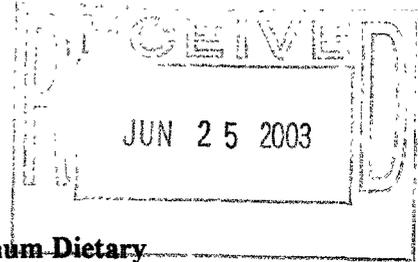


Bayer HealthCare
Consumer Care Division



June 20, 2003

Office of Special Nutritionals
 Center for Food Safety and Applied Nutrition
 U.S. Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740-3835



**Subject: 30-Day Post Market Notification for
 Structure/Function Claims; One-A-Day® Maximum Dietary
 Supplement**

Dear Sir or Madam:

Bayer HealthCare LLC, Consumer Care Division submits the information in this notification pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act as notice of marketing structure/function claims on the product label of One-A-Day® Maximum Dietary Supplement.

Bayer HealthCare LLC
 Consumer Care Division
 36 Columbia Road
 P.O. Box 1910
 Morristown, NJ 07962-1910
 Phone: 973 254-5000

PRODUCT NAME	One-A-Day® Maximum
NAME /ADDRESS OF DISTRIBUTOR	Bayer HealthCare LLC Consumer Care Division 36 Columbia Road P. O. Box 1910 Morristown, New Jersey 07962-1910
NAME OF DIETARY INGREDIENT/ SUPPLEMENT (SUBJECT OF THE STATEMENT)	One-A-Day® Maximum Dietary Supplement Multivitamin/Multimineral Product
TEXT OF STATEMENT BEING MADE	
Top Panel of Carton	Complete Multivitamin designed to help you Maximize Your Day:* <ul style="list-style-type: none"> • Provides Chromium and the full set of B Vitamins necessary to convert food to energy. • Excellent source of Vitamins A, C, E plus Selenium, antioxidants that may be depleted through the stress of intense physical activity. • 100% Daily Value of Vitamins C and Zinc to help support a healthy immune system. • Formulated with an appropriate level of Vitamin A, together with Calcium, Vitamin C, and Vitamin D to help maintain joint and bone health.
5th Panel of Carton	<ul style="list-style-type: none"> • Support physical and mental energy* • Help replace key nutrients lost through the stress of intense physical activity*

975 0162 LET 12325

Right Panel of Carton	Key ingredients to help Maximize Your Day* <ul style="list-style-type: none">• PHYSICAL ENERGY: Chromium, Biotin, Iron, Folic Acid, Vitamin B6, Vitamin B12• MENTAL ENERGY: Vitamin B6, Vitamin B12, Thiamin, Riboflavin, Niacin• IMMUNITY: Vitamins C, A, Selenium, Zinc• STRESS OF PHYSICAL ACTIVITY: Vitamins A, C, E, Selenium• JOINTS AND BONES: Calcium, Magnesium, Zinc, Vitamins A, C, D
Back of Carton	MAXIMUM FORMULA TO HELP KEEP YOU HEALTHY AND ENERGIZED:* <p>The intense physical stress of exercise can create free radicals which can weaken your natural defense system. One-A-Day Maximum's special antioxidant formula, with Vitamins A, C, E, and Selenium, can help maintain your natural defense and immunity. One-A-Day Maximum also includes Chromium and the full set of B vitamins, to help you convert food to physical and mental energy. Complete with 31 important vitamins and minerals, One-A-Day Maximum will help you maintain an active and healthy lifestyle so you can maximize each day.*</p>
*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.	

In accordance with 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer HealthCare LLC, Consumer Care Division has substantiation on file that the statements are truthful and not misleading. This notification is comprised of an original and two (2) copies.

Should you have any questions or need any additional information, please contact the undersigned at 973-254-4793 or MaryRose Salvacion at 973-254-4675.

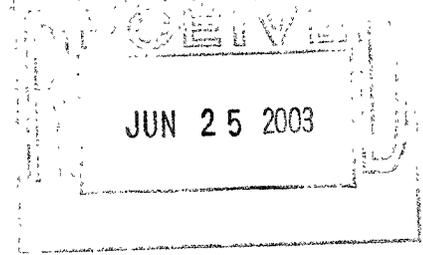
Sincerely,



Catherine W. Fish
Associate Director, Regulatory Affairs
BAYER HEALTHCARE LLC, CONSUMER CARE DIVISION



1735 Connecticut Avenue, NW
Washington, DC 20009
tel 202.518.0200
fax 202.518.8200



Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

**NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT**

On behalf of Unither Nutraceuticals, Inc., the undersigned files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6). The certification required by 21 C.F.R. § 101.93(a)(3) is attached.

Brand Name: HERC™

Dietary Ingredients: Arginine

Statements of Nutritional Support:

- "Increases vasodilation"
- "Supports healthy circulatory function"

Unither Nutraceuticals, Inc.

A handwritten signature in black ink that reads "A. Fisher".

By: Andrew J. Fisher, Corporate Secretary

Attachment – Certification

97S 0162 LET 12324



21 C.F.R. § 101.93(a)(3) Certification

I certify that the information contained in the preceding section 403(r)(6) notice for HERC™ is complete and accurate and that Unither Nutraceuticals, Inc. has substantiation that the statements are truthful and not misleading.

A handwritten signature in black ink, appearing to read "A. Fisher", is written over a horizontal line.

Andrew J. Fisher, Corporate Secretary

June 19, 2003