

Bayer HealthCare
Consumer Care Division



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May 12, 2004

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

MaryRose A. Salvacion
Manager Regulatory Affairs
MAY 14 2004

**Subject: 30-Day Post Market Notification for
Structure/Function Claims; One-A-Day® CarbSmart™**

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® CarbSmart™.

Bayer HealthCare LLC
Consumer Care Division
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910
Phone: (973) 254-4675
Fax: (973) 254-4875

PRODUCT NAME	One-A-Day® CarbSmart™ Multivitamin/Multimineral Supplement
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® CarbSmart™ Multivitamin/Multimineral Supplement
TEXT OF STATEMENT BEING MADE	
5th Panel of Carton	<ul style="list-style-type: none"> Breaks down fats and proteins you eat into energy with more Biotin*
Right Panel of Carton	<p>Key Nutrients to Help Balance Your Low-Carb Diet*</p> <ul style="list-style-type: none"> PROTEIN TO ENERGY: Biotin MUSCLE & BONE HEALTH: Calcium, Magnesium, Potassium, Zinc, Vitamin D, Beta-carotene FAT TO ENERGY: Biotin IMMUNE HEALTH: Zinc, Selenium, Beta Carotene, Vitamin C, Vitamin E HEART HEALTH: Vitamin B12, Vitamin B6, Folic Acid, Vitamin C, Vitamin E
Back of Carton	Plus, One-A-Day CarbSmart contains more Biotin – a key nutrient that helps break down the fats and proteins you're eating into the energy your body needs*.

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***This statement has 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 973-254-4675 or ToniAnn Dudor at 973-254-4778.

Respectfully,



MaryRose A. Salvacion
Manager Regulatory Affairs
BAYER HEALTHCARE LLC, CONSUMER CARE DIVISION