

Consumer Care Division

August 10, 2001

1112 Rec'd AUG 28 P2 53
8/14/01

Bayer Corporation
36 Columbia Road
P.O. Box 1910
Morristown, N.J. 07962-1910
Phone: 201 254-5000

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

**Subject: 30-Day Post Market Notification for Structure/Function Claims;
One-A-Day® Women's Multivitamin/Multimineral Dietary
Supplement**

Dear Sir or Madam:

The following information is an amendment to the 30-Day Post Market Notification for Structure/Function Claims dated 04/30/01 for One-A-Day® Women's Multivitamin/Multimineral Dietary Supplement. For your reference, the original letter is attached to this submission.

The claims submitted in the 04/30/01 submission were incorrectly stated. Bayer 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.

PRODUCT NAME	One-A-Day® Women's
NAME /ADDRESS OF DISTRIBUTOR	Bayer Corporation 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® Women's Multivitamin/Multimineral Dietary Supplement
TEXT OF STATEMENT BEING MADE	<ul style="list-style-type: none"> • NOW WITH MORE BONE-BUILDING NUTRIENTS* • Optimal VITAMIN A levels scientifically formulated to maintain maximum bone strength.* • Now more bone-building nutrients – including MAGNESIUM, CALCIUM and VITAMIN D.*
*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.	

Per the listed items in 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer Consumer Care Division has substantiation, on file, that the statement is truthful and not misleading. This notification is comprised of an original and two (2) copies.

**30-Day Post Market Notification for Structure/Function Claims;
One-A-Day® Women's Multivitamin/Multimineral Dietary Supplement
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Should you have any questions or need any additional information, please contact the undersigned at 973-254-4793.

Sincerely,

A handwritten signature in cursive script that reads "Catherine W. Fish".

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



Consumer Care Division

Bayer Corporation
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910
Phone: 973 254-5000

April 30, 2001

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

30-day Post Market Notification

PRODUCT NAME:	One-A-Day® Women's
NAME /ADDRESS OF DISTRIBUTOR	Bayer Corporation Consumer Care Division 36 Columbia Road P. O. Box 1910 Morristown, New Jersey 07962-1910
NAME OF DIETARY INGREDIENT/SUPPLEMENT (SUBJECT OF THE STATEMENT):	TEXT OF STATEMENT BEING MADE:
One-A-Day® Active One-A-Day® Active (Ginseng Standardized Extract) (Panax quinquefolius) (root)	•More cell protective antioxidants Vitamin C and E plus Beta Carotene and Selenium* •More essential B vitamins for energy metabolism plus Chromium to help your body regulate fuel stores for energy*
*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 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	

Per the listed items in 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer Consumer Care Division has substantiation, on file, that the statement is truthful and not misleading. (This notification is comprised of an original and two (2) copies.)

Anita Fenty
Regulatory Affairs Manager