

Eleanor F. Barbo Senior Director, Regulatory Affairs

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June 19, 2

Centrum®

## Notification of Statements on Dietary Supplement Labels

Dr. Robert Moore, Branch Chief
Dietary Supplements Branch (HFS-811)
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling, and Dietary Supplements
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Dear Dr. Moore:

Reference is made to Centrum<sup>®</sup> Single Entities, marketed by Whitehall-Robins Healthcare ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for structure/function statements made on the dietary supplement products listed in Attachment A.

The company name and address for all products listed in Attachment A is as follows:

Whitehall-Robins Healthcare Five Giralda Farms Madison, New Jersey 07940-0871

In accord with 21 CFR §101.93, the disclaimer statement is bolded and boxed on the front panel of all labels where structure/function claims appear.

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The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE

Eleanor F. Barbo Senior Director Regulatory Affair

## Attachment A

Product Name	Ingredient	Statements on Label
Vitamin B <sub>6</sub>	Vitamin B <sub>6</sub>	Helps maintain normal protein metabolism.
100 mg		. Important for nervous system function.
Vitamin B <sub>12</sub>	Vitamin B <sub>12</sub>	Helps build red blood cells.
500 mcg		. Helps maintain normal nervous system function.
Vitamin B <sub>12</sub>	Vitamin B <sub>12</sub>	Helps build red blood cells.
1000 mcg		. Helps maintain normal nervous system function.
Vitamin B100	Thiamin,	Provide the body with energy by converting
Complex	Riboflavin,	carbohydrates into glucose.
*	Niacin,	. Important for normal nervous system function.
	Vitamin B <sub>6</sub> ,	
	Folic Acid,	
	Vitamin B <sub>12</sub> ,	
	Biotin,	
	Pantothenic	
	Acid	
Folic Acid	Folic Acid	. A key nutrient required during child bearing years.
400 mcg		
Vitamin C	Vitamin C	. Important for proper immune system function.
250 mg		. Works with Vitamin E to help prevent LDL oxidation,
		which may help maintain a healthy circulatory system.
		Essential for healthy teeth, gums, and bones.
Vitamin C	Vitamin C	. Important for proper immune system function.
500 mg		. Works with Vitamin E to help prevent LDL oxidation,
		which may help maintain a healthy circulatory system.
		Essential for healthy teeth, gums, and bones.
Vitamin C	Vitamin C	Important for proper immune system function.
1000 mg		Works with Vitamin E to help prevent LDL oxidation,
		which may help maintain a healthy circulatory system.
		Essential for healthy teeth, gums, and bones.
Chewable	Vitamin C	Important for proper immune system function.
Vitamin C		. Works with Vitamin E to help prevent LDL oxidation,
250 mg		which may help maintain a healthy circulatory system.
		Essential for healthy teeth, gums, and bones.
Chewable	Vitamin C	Important for proper immune system function.
Vitamin C		Works with Vitamin E to help prevent LDL oxidation,
500 mg		which may help maintain a healthy circulatory system.
****		Essential for healthy teeth, gums, and bones.
Vitamin E	Vitamin E	. May help maintain a healthy circulatory system by
400 IU		helping to prevent LDL oxidation.
		<ul> <li>Helps prevent the destruction of red blood cells.</li> </ul>

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Vitamin E 1000 IU	Vitamin E	<ul> <li>May help maintain a healthy circulatory system by helping to prevent LDL oxidation.</li> <li>Helps prevent the destruction of red blood cells.</li> </ul>
Natural Vitamin E 400 IU	Vitamin E	<ul> <li>May help maintain a healthy circulatory system by helping to prevent LDL oxidation.</li> <li>Helps prevent the destruction of red blood cells.</li> </ul>
Water Dispersible Vitamin E 200 IU	Vitamin E	<ul> <li>May help maintain a healthy circulatory system by helping to prevent LDL oxidation.</li> <li>Helps prevent the destruction of red blood cells.</li> </ul>
Water Dispersible Vitamin E 400 IU	Vitamin E	<ul> <li>May help maintain a healthy circulatory system by helping to prevent LDL oxidation.</li> <li>Helps prevent the destruction of red blood cells.</li> </ul>
Beta Carotene 25,000 IU	Vitamin A as Beta Carotene	<ul> <li>Antioxidant that helps maintain normal eye and immune function.</li> </ul>
Iron 25 mg	Iron	<ul><li>Vital for cells to generate energy.</li><li>Essential for the formation of blood.</li></ul>
Magnesium 200 mg	Magnesium	<ul><li>Essential in converting blood sugar into energy.</li><li>Essential for effective nerve and muscle function.</li></ul>
Potassium 99 mg	Potassium	<ul><li>Helps maintain normal heart muscle function.</li><li>Supports water balance within the body.</li></ul>
Selenium 200 mcg	Selenium	<ul> <li>Essential component of the body's antioxidant defense system.</li> <li>Helps protect cells from damage caused by free radicals.</li> </ul>
Zinc 30 mg + Copper 4 mg	Zinc, Copper	<ul><li>Helps maintain the body's natural defense system.</li><li>Vital for normal growth and development.</li></ul>
Calcium 600 mg + Vitamin D	Vitamin D, Calcium Carbonate	<ul><li>Helps maintain strong bones.</li><li>Helps regulate heartbeat.</li></ul>
Calcium 250 mg with Vitamin D and Minerals	Vitamin D, Calcium Citrate, Magnesium, Zinc, Copper, Manganese, Boron	<ul> <li>Helps maintain strong bones.</li> <li>Helps regulate heartbeat.</li> </ul>
Calcium, Magnesium and Zinc + Other Trace Minerals	Vitamin D, Calcium, Magnesium, Zinc, Copper, Manganese, Boron	<ul> <li>Helps maintain strong bones.</li> <li>Calcium plus six additional nutrients, essential for healthy bone formation.</li> </ul>

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Chromium	Chromium	. Aids in proper Glucose metabolism.
Picolinate	Picolinate	. Aids in carbohydrate, protein, and fat metabolism.
Coenzyme Q10	Coenzyme	. Antioxidant that helps protect against free radical
60 mg	Q10	damage.
		•
Omega 3 Fatty	Fish oil	Helps maintain heart health.
Acids	providing	
	EPA and	
	DHA	
Complete	Vitamin A,	. Helps protect cells from free radical damage caused by
Antioxidant	Vitamin C,	environmental and physical stress.
Formula	Vitamin E,	. May help maintain heart, eyes, and immune function.
	Zinc,	
	Selenium,	
	Copper,	
	Manganese	