

## SOLGAR VITAMIN AND HERB

WORLD HEADQUARTERS

500 WILLOW TREE ROAD, LEONIA, NJ 07

UALITY PLEDGE

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-May 29, 2001

Mr. John B. Foret - Director
Division of Compliance & Enforcement
Office of Nutritional Products, Labeling & Dietary Supplements
Food & Drug Administration - Center for Food Safety & Applied Nutrition
200 "C" Street, S.W.
Washington, DC 20204

Reference: Food & Drug Administration Correspondence dated May 16, 2001.

Dear Mr. Foret:

Reference is made to your letter of May 16, 2001 commenting on label claims for Naturvite Natural Vitamins Folic Acid 400 mcg and Women's Multiple submitted by letter dated April 19,2001 pursuant to 21 CFR 343(r)(6)(section 403(r)(6). Specifically that the statement: "...reduce the risk of having a child born with neural tube defects", is not of nutritional support but is a health claim.

The claims on both labels will be changed to those authorized by the FDA in 21 CFR 101.79.

- 1. For Naturvite Women's Multiple (533 mcg folic acid, 133% DV):
- "Women who consume healthful diets with adequate Folic Acid may reduce their risk of having a child with birth defects of the brain or spinal cord."

will replace,

- "...Folic Acid which may reduce the risk of having a child with neural tube birth defects;...."
- 2. For Naturvite Folic Acid 400 mcg (100% DV):
- "Adequate Folic Acid in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect."

will replace,

"Folic Acid may reduce the risk of having a child born with neural tube birth defects."

Please feel free to contact me if you require further information.

Yours truly,

William Coogan

Manager cGMP Compliance

Solgar Vitamins & Herb

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