



Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-810
200 C Street, S.W.
Washington, DC 20204
202-205-5229

August 14, 2000

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

"Enhances Glutathione and Supports Liver Function" – ThioNAC is a combination of the thiols N-Acetyl -L-Cysteine (NAC) and Alpha Lipoic Acid, which are sulfhydryl antioxidants. NAC is the rate-limiting amino acid used in the production of the critical antioxidant glutathione which is made intracellularly primarily in liver cells. Alpha lipoic acid is accessible to lipid and water soluble cellular compartments and able to regenerate glutathione and vitamins E & C. Alpha lipoic acid is an important mitochondrial cofactor for the production of energy from pyruvate.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Combination of N-Acetyl Cysteine and Alpha Lipoic Acid

(4) Name of the dietary supplement(s)

ThioNAC (60 Sustained Release Tablets)

(5) The following disclaimer appears on the label in bold: 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 claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Siddharth Shastri, CCN

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