



RECEIVED
8/4/04
June 30, 2004

Dr. Robert Moore
Division of Compliance and Enforcement/ONPLDS
Center for Food and Safety and Applied Nutrition
U.S. Food and Drug Administration
HFS - 810
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Moore:

Inverness Medical Nutritionals Group has launched a new dietary supplement and wishes to notify the Food and Drug Administration. The supplement, *Metaboless Ultimate (or Metabowise Ultimate)*, consists of the active ingredients (per 2 caplets) Thiamin (as thiamin mononitrate) 1.5 mg, Riboflavin 1.7 mg, Niacin (as niacinamide) 20 mg, Vitamin B6 5 mg, Pantothenic Acid 10 mg, Calcium (as hydroxycitrate and as dicalcium phosphate) 60 mg, Sodium (as sodium chloride) 30 mg, Potassium (as potassium chloride) 80 mg, Garcinia extract 850 mg, and a Proprietary Blend 398 mg containing Guarana extract, Taurine, and Bitter Orange extract. This product also contains 55 mg of caffeine per caplet and bears the following structure / function claims on the label(s).

Display Panel (Bottle Label)

To Enhance Energy and Diet*

* 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.

97S 0162

LET

Page 1 of 2

14479

89279

Side Panel (Bottle Label)

It also contains the following warning:

WARNING: Do not take if pregnant or nursing. Not for use by or sale to persons under age 18. Consult a physician or licensed qualified healthcare professional ("physician") prior to use if you have, or have a family history of heart or thyroid disease, diabetes, high blood pressure, recurrent headaches, depression, any psychiatric condition, glaucoma, difficulty urinating, enlarged prostate, seizure disorder, if you are using any prescription drug, a monoamine oxidase inhibitor (MAOI), or any other dietary supplement, prescription drug, or over-the-counter drug containing ephedrine, pseudoephedrine or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold, and weight control products). Discontinue use and call a physician immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms. Exceeding recommended servings may cause serious adverse health effects. The recommended serving of this product contains about as much caffeine as 2 cups of coffee. Limit the use of caffeine containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, sleeplessness, and occasionally rapid heart beat. Caution, skin may become sensitive when exposed to the sun. **KEEP OUT OF THE REACH OF CHILDREN.**

We certify that the information contained in this notice is complete and accurate, and we have substantiation that the above structure/function statements are truthful and not misleading.

Sincerely,



William J. Neumann
Vice President
Quality and Regulatory Affairs