



**inverness medical**

nutritionals group

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April 27, 2005

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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, pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93.

The supplement, *CorLene (or CorSystem)* consists of the following active ingredients (per 1 capsule): Vitamin C (as calcium ascorbate) 100 mg, Calcium (as calcium carbonate & calcium ascorbate) 150 mg, Chromium (as chromium polynicotinate) 50 mcg; and Proprietary Blend 1 (Magnolia Bark extract [40% Honokiol], Beta-Sitosterol, L-Theanine) 58.75 mg; Proprietary Blend 2 (Green Tea extract [45% EGCG], Korean Ginseng extract [4.5% Ginsenosides]) 125 mg; Proprietary Blend 3 (Banaba Leaf extract [1% Corosolic Acid], Vanadyl Sulfate [providing 5 mcg of Vanadium]) 16.5 mg, and will bear the following structure/function statements on the label.

Helps in Stress Management\*

Take CorLene (CorSystem) everyday as part of your healthy diet and exercise regimen.

**\* 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.**

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

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