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Office of Nutritional Products Labeling  
and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740

MAR 25 2004

Re: Notification for Statement on Dietary Supplement Labels

Dear Sir/Madam:

This notification is being submitted on behalf of EuroPharma, Inc., Green Bay, Wisconsin, a distributor of dietary supplement products.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), and in accordance with the authorized provisions of 21 CFR § 101.93(a), your Agency is hereby notified that EuroPharma, Inc. has made statements of "nutritional support", as described in 21 U.S.C. § 343(r)(6)(A), for its dietary supplement(s) as follows:

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>
<p><b>Body Confident Cellulite Formula™</b></p>	<p><b>Cellulite affects women of every size, shape, and weight, often resisting the strictest diets and most structured exercise programs. Gain control over cellulite and improve skin's texture, softness, and smoothness with Body Confident Cellulite Formula™.*</b></p> <p>Cellulite Formula™ features an Exclusive Anti-Dimpling Blend™ to help the body metabolize fat, shrinking undesirable fatty deposits under the skin's surface. Artichoke extract enhances bile flow from the liver while coleus extract enhances the metabolism of fat for energy. In addition, the blend contains lipase, an enzyme the body uses to break down fat.*</p> <p>The Exclusive Anti-Dimpling Blend™ features grape seed extract, standardized for polyphenols that protect collagen from free radicals and stimulate its regeneration. The extract has a high flavonoid content to strengthen capillaries and small veins that deliver blood and nutrients to tissue. Gotu kola extract maintains skin's underlying structure to rejuvenate skin and tissue.*</p> <p>The antioxidant properties of horse chestnut extract have been shown to protect the liver. Optimal liver function helps to support the body's natural elimination of toxins, one of the factors believed to contribute to cellulite. Horse chestnut extract—particularly its active ingredient, escin— maintains connective tissue tone and promotes circulation.*</p> <p>97S 0162 LET 13848</p>



<u>PRODUCT NAME</u>	<u>STATEMENTS</u>
<b>Body Confident Cellulite Formula™</b>	<p>Sweetclover's key active ingredient, coumarin, diminishes the appearance of cellulite by supporting lymphatic drainage.*</p> <p>In addition, Ginkgo biloba Dimeric Phytosome™ has been shown to support microcirculation in the skin. This promotes the mobilization of fluids in the skin.*</p> <p>Supports the body's fat metabolism to help shrink fatty deposits under the skin's surface.*</p> <p>Strengthens collagen structure and maintains connective tissue tone.*</p> <p>Enhances microcirculation in skin, which maintains connective tissue strength and supports lymphatic drainage.*</p>

As required, enclosed are two photocopies of this notification.

The undersigned certifies on behalf of EuroPharma, Inc. that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,  
EuroPharma, Inc.

By: Terrence Lemerond  
Its: President