

2/20/04

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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 - 8 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:

<b>PRODUCT NAME</b>	<b>STATEMENTS</b>
<p><b>Body Confident Advanced Breast Formula™</b></p>	<p><b>Society's attention may focus on breast size. But Body Confident Advanced Breast Health Formula™ concentrates on what matters most – supporting a healthy foundation at every age.*</b></p> <p>Advanced Breast Health Formula™ features an Exclusive Healthy Shape Blend™ of superior herbal extracts and antioxidants to offer maximum support for breast tissue health. These extracts promote healthy hormone balance and support underlying breast structure.*</p> <p>Many of the herbs featured in the Exclusive Healthy Shape Blend™ have been studied for their phytoestrogenic effects. They help maintain a healthy hormone balance in the body and support breast health and shape.*</p> <p>Phytoestrogens are of special interest to women of all ages. Phytoestrogens support hormone function and balance in the body. Variations in hormone levels can affect the health and structure of underlying breast tissue. With age, the breasts' connective tissue can become dehydrated and inelastic.*</p> <p>The plant-derived compounds in Advanced Breast Health Formula™ include pomegranate extract, which offers superior antioxidant properties and supports breast cellular structure. The ellagic acid in the extract has been shown to effectively protect cells from damaging free radicals. Specifically, pomegranate contains anthocyanidins, which are powerful free radical scavengers.*</p>

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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>
<b>Body Confident Advanced Breast Formula™</b>	<p><b>Advanced Breast Health Formula™ also features borage seed and pumpkin seed oils standardized for essential fatty acids (EFAs). These valuable oils provide gamma linolenic and linoleic acids, which are crucial to supporting overall hormonal health and cellular structure.*</b></p> <p>Pomegranate extract provides powerful antioxidants to protect breast health at the cellular level and support underlying breast structure.*</p> <p>The Exclusive Healthy Shape Blend™ features herbs studied for their phytoestrogenic effects, particularly for cellular health. This blend helps maintain a healthy hormone balance, which in turn supports breast health and shape.*</p> <p>Borage seed and pumpkin seed oils provide gamma linolenic and linoleic acids crucial to overall hormonal health.*</p>

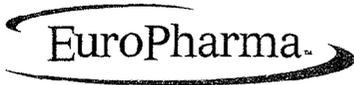
As required, enclosed are two photocopies of this notification.

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



**COPY**

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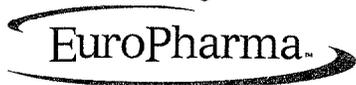
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>
<b>Body Confident Advance Breast Health Formula™</b>	<b>Diminishes the Appearance of Fine Lines and Wrinkles.*</b>  Body Confident Advanced Breast Health Formula™ naturally and powerfully supports women's breast health as they age. The <i>Exclusive Healthy Shape Blend™</i> of superior herbal extracts and antioxidants protect underlying breast structure and health. The standardized pomegranate extract offers both phytoestrogenic and antioxidant effects. Additional ingredients maintain a healthy balance of estrogen and progesterone, supporting breasts' cellular health and shape. Borage and pumpkin seed oils provide essential fatty acids crucial to supporting hormonal health at every age.*

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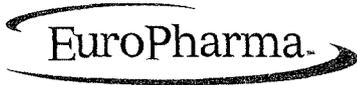
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>
<b>Body Confident Advance Breast Health Formula™</b>	<b>Supports Underlying Breast Structure and Health.*</b>  Body Confident Advanced Breast Health Formula™ naturally and powerfully supports women's breast health as they age. The <i>Exclusive Healthy Shape Blend™</i> of superior herbal extracts and antioxidants protect underlying breast structure and health. Vital ingredients maintain a healthy balance of estrogen and progesterone, supporting breasts' cellular health and shape. Borage and pumpkin seed oils provide essential fatty acids crucial to supporting hormonal health at every age.*

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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>
<b>Body Confident Advance Breast Health Formula™</b>	<b>This product targets anyone who wants to support breast tissue structure and health. It's especially important for women who have lost or gained weight, been pregnant, or who are growing older, as these are common factors in breast sagging.*</b>

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EuroPharma, Inc.

By: Terrence Lemerond  
Its: President