



11/3/03

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

Re: Notification Or 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:

PRODUCT NAME	STATEMENTS
Echinacea 365™	<p>The healthy Echinacea for ongoing use.*</p> <p>IBA-Free.</p> <p>Echinacea 365™ features a triple-standardized Echinacea that contains a newly discovered poly-saccharide to enhance T-cell activity. The T-cell Activator Blend™ is proven more effective than the leading European Echinacea product. Echinacea 365™ is also IBA-free, so it can be used long term.*</p> <p>Echinacea 365™ features a triple-standardized Echinacea for optimum support when you need it most. This <i>Echinacea angustifolia</i> extract is standardized for 4% echinacosides and a newly discovered polysaccharide to enhance T-cell activity. This extract is free of isobutylamides (IBAs), a compound in Echinacea that can be toxic and limit its long-term use. Other Echinacea products recommend taking periodic breaks from their use. Because Echinacea 365™ is IBA-free, it can be used long term.*</p> <p>The Exclusive T-Cell Activator Blend™ combines <i>Echinacea angustifolia</i> with two herbal extracts that work synergistically - Astragalus and Ligustrum Extracts. Both have been used for thousands of years in traditional Chinese medicine. The blend has been studied and proven more effective than the leading European Echinacea product.*</p>

As required, enclosed are two photocopies of this notification.

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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.

A handwritten signature in black ink, appearing to read "Terrence Lemerond". The signature is fluid and cursive, with a prominent initial "T" and a long, sweeping underline.

By: Terrence Lemerond  
Its: President