

EuroPharma

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

044 - 100

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:

PRODUCT NAME	STATEMENTS
Low Back Rescue™	<p>Reduces minor low back muscle pain and stiffness.*</p> <p>Low Back Rescue™ is ideal for those who experience mild low back muscle stiffness due to strenuous activity, exercise, or overuse. The Exclusive Free Movement Blend™ features Devil's Claw Extract and a unique Purple Willow Bark Extract, both of which have been shown in double-blind studies to reduce lower back pain. The featured Purple Willow Bark Extract undergoes a special patented process to retain its full spectrum of key compounds. These include critical polyphenols, which are destroyed in other willow extracts. Together, these extracts relieve minor low back muscle soreness, stiffness, and pain without side effects.*</p> <p>The formula also features manganese, a nutrient necessary for healthy skin, bone, and cartilage formation, and which supports superoxide dismutase (SOD). SOD is an antioxidant enzyme that prevents oxidative damage that destroys collagen and other structural components in the body. Both manganese and vitamin C aid in collagen formation, which supports muscle strength.*</p>

As required, enclosed are two photocopies of this notification.

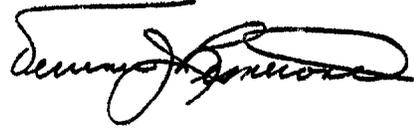
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The undersigned certifies on behalf of EuroPharma, Inc. that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,
EuroPharma, Inc.

By: Terrence Lemerond
Its: President

A handwritten signature in black ink, appearing to read "Terrence Lemerond", written in a cursive style.