



SEP 29 2004

Mr. Terrence Lemerond
President
EuroPharma, Inc.
P.O. Box 22547
Green Bay, Wisconsin 54305-2547

Dear Mr. Lemerond:

This is in response to your letter of September 17, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that EuroPharma, Inc. is making the claims identified below for the product **LitoZin™**.

The product **LitoZin™** uses the claim “[R]educing pain due to everyday activity.” This claim is a disease claim because it suggests that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis, when considered in the context of the other claims regarding the promotion of joint health, mobility, comfort, and cartilage integrity and C-reactive protein levels. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that “joint pain” is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there “normal pain levels,” a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

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The claim contained in your notification does not refer to pain associated with a non-disease state. Although "everyday activities" are not themselves diseases, they would not be expected to result in joint pain unless a person already suffered from an underlying disease that predisposed him or her to such pain.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S. Walker", with a long horizontal line extending to the right.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-CE840



09/17/04

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

RECEIVED
SEP 21 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:

PRODUCT NAME	STATEMENTS
LitoZin™	Promotes joint health, mobility and comfort Protects the integrity of cartilage and promotes joint health and comfort Joint support and antioxidant properties Supports healthy C-reactive protein levels Promotes mobility and comfort by reducing pain due to everyday activity

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

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