

McLind Corporation

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RECEIVED
JAN 07 2002
BY:

November 19, 2001

John B. Foret
Director, Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center of Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W.
Washington, D.C. 20204

RE: Arthrenew

Dear Mr. Foret:

McLind Corporation wishes to notify the Food and Drug Administration that it is making changes to the dietary supplement label for the product Arthrenew. This change is based on your letter dated October 25, 2001, attached hereto. In order to comply with the requirements of 21 U.S.C. 343(R)(6), the statements on the label have been changed. The original statement and changes read as follows:

~~"Ultimate Joint Support Powder. Its unique powder formula includes the building blocks and cofactors for healthy cartilage and connective tissue. Plus, it contains powerful herbal extracts for the relief of minor aches and pains antioxidant herbal extracts to help maintain maximal joint flexibility.~~

~~For the relief of minor aches and pains,~~ To help maintain maximum joint flexibility, Arthrenew contains three potent herbal extracts: boswellia serrata gum extract, tumeric extract and ginger extract.

This statement is accompanied by the required disclaimer, which is prominently displayed in bold-faced type.

This information contained in this notice is complete and accurate and the above statement is based on data, which renders these statements substantiated, truthful and non-misleading.

Sincerely,
McLind Corporation



Douglas McFarland, M.D.
Director, Product Development

975-0162

LET 8945



OCT 25 2001

Douglas McFarland, M.D.
Director, Product Development
McLind Corporation
2575 West 237th Street
P.O. Box 3669
Torrance, California 90510-3669

Dear Dr. McFarland:

This is in response to your letter of October 5, 2001 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 McLind Corporation is making the following claim, among others, for the product **Arthrenew**:

“...for the relief of minor aches and pains.”

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, because it is made in the context of other claims that the product is “used for joint health” and to “help repair cartilage in joints,” suggests that it is intended to treat, prevent, cure, or mitigate diseases, namely, arthritis or other joint disorders.¹ 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, 7520 Standish Place, Rockville, Maryland 20855.

¹See discussion regarding claims related to pain relief in the January 6, 2000 Federal Register (65 FR 1000 at 1016 (comment 41) and at 1030 (comment 83)).

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

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-300

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

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240