DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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.

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[1]See 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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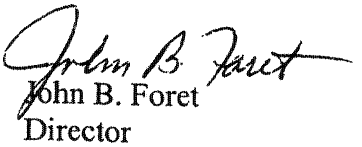
Please contact us if we may be of further assistance.

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

McLind Corporation

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October 5, 2001

Linda S. Kahl, Ph.D.
Office of Special Nutritionals (HFS-450)
Center of Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W.
Washington, D.C. 20204

Dear Dr. Kahl:

McLind Corporation wishes to notify the Food and Drug Administration that it plans to commence marketing a dietary supplement, which bears a statement under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statements are made is Arthrenew. The dietary ingredients that are the subject of the statements are Glucosamine sulfate, Chondroitin sulfate, Methyl sulfonyl methane (MSM), Tumeric, Ginger, Boswellia serratia. The statements 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.

Each serving combines 1,500 mg Glucosamine sulfate and 1,200 mg Chondroitin sulfate. Recent research has shown they can actually help repair cartilage in joints.

We then add 1,000 mg MSM, an easily absorbed source of sulfur and 1,000 mg of Vitamin C. Both are critical for healthy collagen and connective tissue production.

For the relief of minor aches and pains, Arthrenew contains three potent herbal extracts: boswellia serrata gum extract, tumeric extract and ginger extract. For more relief, we have added bromelain, an enzyme extracted from pineapple that is traditionally used for joint health.

Long considered an "anti-stress" vitamin, each serving of Arthrenew contains 50 mg of pantothentic acid. This vitamin is essential for the normal production of you body's adrenal hormones."

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

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