



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

3619 01 MAR 16 A7:16
FEB 22 2001

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

Dear Dr. McFarland:

This is in response to your letter to the Food and Drug Administration (FDA), dated December 12, 2001, 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 **Acetyl L-Carnitine**:

“...widely studied for its effects on brain function and depression.”

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, namely depression. 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. 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

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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, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-810
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson)
f/t:rjm:HFS-811:1/30/01:73973.adv:disc53

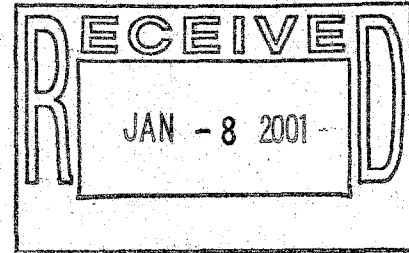
McLind Corporation

Mailing Address: P.O. Box 3669, Torrance, CA 90510-3669
Business Address: 2575 West 237th Street, Torrance, CA 90505

Business: (310) 784-8500
Fax: (310) 784-8528

December 12, 2000

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 has, within the past 30 days, commenced 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 statement is made is Acetyl L-Carnitine. The dietary ingredient that is the subject of the statement is acetyl L-carnitine. The statement reads as follows.

"Acetyl-L-Carnitine has been widely studied for its effects on brain function and depression." "Brain and Mood Support."

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