



FEB - 4 2005

Mr. Don McFarland  
President  
McLind Corporation  
P.O. Box 3669  
Torrance, California 90510-3669

Dear Mr. McFarland:

This is in response to your letters of January 24, 2005 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 letters state that the following statements, among others, will be made for one or more of the products Lindberg Niacin (100 mg), Lindberg Prolonged Release Niacin (500 mg), Lindberg No-Flush Niacin (500 mg), Policosanol (20 mg), and Lindberg Garlic (500 mg).

“[P]romotes health cholesterol levels....”  
“Cholesterol Support Category”  
“[F]or cholesterol support...”  
“[S]upport healthy cholesterol...”  
“[S]upport healthy L:DL...levels...”  
“[Maintain healthy...cholesterol levels...”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claims you are making for these products represent that the products are intended to affect blood cholesterol but do not also include a statement about them being intended to affect blood cholesterol that is already in the normal range, they are implied disease claims.

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products

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Page 2 - Mr. Don McFarland

are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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 "Susan J. Walker" with a stylized flourish at the end. Below the signature, the letters "FOR" are written in a smaller, simpler font.

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

# 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

January 4, 2005

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

OFFICE

JAN 24 2005

Re: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

McLind Corporation, P.O. Box 3669 Torrance, CA 90510-3896, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

“Promotes Heart and General Health\*\*”

“Garlic has been used medicinally for thousands of years. It can help maintain healthy triglycerides and cholesterol levels, supporting heart health.\*\*”

These claims are being made for a product named Lindberg® Garlic 500 mg. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the McLind Corporation and certifies that the information contained in this notice is complete and accurate, and that McLind Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

By:

  
Don McFarland  
President

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JAN 27 2005

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To Whom It May Concern:

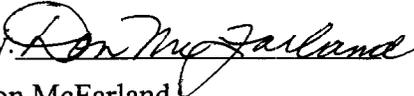
McLind Corporation, P.O. Box 3669 Torrance, CA 90510-3896, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

“Cholesterol Support Category\*”

“Policosanol is a mixture of nine different aliphatic alcohols designed to support healthy cholesterol. Octacosanol, a derivative of the wax from sugar cane plants, is the main ingredient in policosanol and works as a powerful antioxidant to help maintain healthy arteries. This, combined with the actions of eight other alcohols, can support healthy LDL and HDL levels, promoting cardiovascular health.\*”

These claims are being made for a product named Lindberg® Policosanol 20 mg. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the McLind Corporation and certifies that the information contained in this notice is complete and accurate, and that McLind Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

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McLind Corporation, P.O. Box 3669 Torrance, CA 90510-3896, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

“Cholesterol Support Category\*”

“Niacin has long been a popular supplement used for healthy cholesterol support, but many users often complain about the “niacin flush” that accompanies its use. Our vegetarian formula No-Flush Niacin, also known as inositol hexanicotinate, is a form of niacin that provides all of the same benefits as traditional niacin without the flush. This is possible because the body metabolizes inositol hexanicotinate slower than traditional niacin, not reaching full serum levels for nearly 10 hours.\*”

These claims are being made for a product named Lindberg® No-Flush Niacin 500mg. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the McLind Corporation and certifies that the information contained in this notice is complete and accurate, and that McLind Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

By:   
Don McFarland  
President

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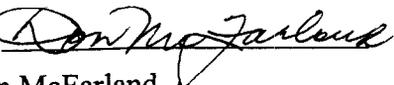
McLind Corporation, P.O. Box 3669 Torrance, CA 90510-3896, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

“Supports Energy Production\*”

“One of the B Vitamins, Niacin promotes healthy cholesterol levels and supports energy production.\*”

These claims are being made for a product named Lindberg® Prolonged Release Niacin 500 mg. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the McLind Corporation and certifies that the information contained in this notice is complete and accurate, and that McLind Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

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McLind Corporation, P.O. Box 3669 Torrance, CA 90510-3896, who is the distributor of the following dietary supplement product, intends to make the following statement(s) of support:

“Essential for Energy Production\*”

“One of the B Vitamins, Niacin promotes healthy cholesterol levels and supports energy production.\*”

These claims are being made for a product named Lindberg® Niacin 100mg. This submission is being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the McLind Corporation and certifies that the information contained in this notice is complete and accurate, and that McLind Corporation has substantiation that the above statement(s) is (are) truthful and not misleading.

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