



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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AUG - 7 2007

Ms. Erin Silva
Technical Marketing Manager
Vitamer Labs
46 Corporate Park, Suite 100
Irvine, California 92606

Dear Ms. Silva:

This is in response to your letter of June 27, 2007 on behalf of your client McLind Corp. of Torrance, California. Your letter responded to our May 16, 2007 letter to McLind concerning claims they notified the agency that they intended to use in the labeling of their dietary supplement product called Inflatrol™.

In our May 16, 2007 letter, we stated that the claims "Excessive, chronic inflammation in the body may lead to deleterious effects, including chronic disease. Diet...determine disease development and progression" and "Inflatrol...may help support a healthy inflammation response" suggested that the product is intended to treat, prevent, or mitigate a disease, namely chronic inflammation, and that the product that was the subject of the claims appeared to be subject to regulation under the drug provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

In your letter, you presented a proposed revised claim that reads:

"Chronic inflammation is the body's abnormal prolonged and excessive response to an initial injury or infection. A healthy diet and exercise are two factors within our control to help maintain our health. Inflatrol™ combines natural plant ingredients that offer vitamins, antioxidants and phytonutrients to support overall health and an active lifestyle. Turmeric (an Indian spice) contains a beneficial compound called curcumin, which has been shown to have antioxidant activity and other properties to support healthy tissues. Bromelain (from pineapple) and papain (from papaya) are two plant enzymes with protein-digesting activity. Quercetin is a natural occurring bioflavonoid shown to promote blood vessel health. Our green tea extract contains a standardized, high polyphenol (especially EGCG) content to offer a powerful source of both antioxidants and phytonutrients."

You state in your letter that, as written, "the claim simply defines chronic inflammation in physiological terms then states general principles one can follow to support good health. The text goes on to list and describe the various ingredients in the product without implication to any effect on inflammation." Accordingly, your letter puts forth your belief that the revised

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claim is within the scope of claims that may be made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Act).

We disagree with your assertion that the revised claim is not a disease claim. The claim begins with a description of chronic inflammation, a condition that is unambiguously a disease as that term is defined in 21 CFR 101.93(g)(1), and then describes factors within one's own control that are useful to "help maintain our health," beginning with a healthy diet. In the context of the preceding sentence describing chronic inflammation, the reference to the role of diet in health maintenance implies that diet (including dietary supplements such as Inflatrol™) plays a role not only in helping to maintain general health but also, more specifically, in preventing chronic inflammation. The statement about the role of diet in helping to maintain health, with its implied reference to preventing chronic inflammation, is immediately followed by a description of your product, Inflatrol™, which is marketed as a dietary supplement, and of the benefits of Inflatrol™ and its ingredients to health maintenance. The claim also describes a specific ingredient of the product (i.e., turmeric) as beneficial to the support of healthy tissues. Taken together, the description of chronic inflammation, a disease that directly affects various tissues, followed by the express description of the product and its ingredients as beneficial for helping to maintain health, including maintenance of healthy tissues, evidence that the intended use of this product is to treat, prevent, or mitigate a disease.

We are not persuaded that the position set forth in our May 16, 2007 letter to McLind is incorrect. We believe that, for the reasons set forth above, that the claim proposed for this product implicitly represents Inflatrol™ for use in the treatment, cure, prevention, mitigation of chronic inflammation and that the product is, therefore, subject to regulation as a drug.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, 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-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

Copy:

Mr. Don McFarland

President

McLind Corporation

PO Box 3669

Torrance, California 90510-3669

June 27, 2007

Vasilios H. Frankos, Ph.D
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, D.C. 20204



Dear Dr. Frankos,

On May 16, 2007, you sent a letter to our customer, Mr. Don McFarland, President of McLind Corporation stating that the McLind Corporation made claims on a dietary supplement that suggested the product is intended for use as a drug within the meaning of 21 U.S.C.321(g)(1)(B).

As the private label manufacturer of the product in question for McLind Corporation, we have responded by changing the product's label text to the following:

"Chronic inflammation is the body's abnormal prolonged and excessive response to an initial injury or infection. A healthy diet and exercise are two factors within our control to help maintain our health. Inflatrol™ combines natural plant ingredients that offer vitamins, antioxidants and phytonutrients to support overall health and an active lifestyle. Turmeric (an Indian spice) contains a beneficial compound called curcumin, which has been shown to have antioxidant activity and other properties to support healthy tissues. Bromelain (from pineapple) and papain (from papaya) are two plant enzymes with protein-digesting activity. Quercetin is a naturally occurring bioflavonoid shown to promote blood vessel health. Our green tea extract contains a standardized, high polyphenol (especially EGCG) content to offer a powerful source of both antioxidants and phytonutrients."

We believe this is not an implied drug claim because it does not claim to diagnose, mitigate, treat, cure, or prevent disease under 21 U.S.C. 343(r)(6) Specifically, this claim:

- (i) does not have an effect on a specific disease or class of diseases;
- (ii) does not have an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;
- (iii) it does not have an effect on an abnormal condition associated with a natural state or process;
- (iv) it does not have an effect on a disease or diseases through any of the factors listed in (A)-(E) of 21 CFR 101.93(g)(2)(iv);
- (v) it does not belong to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;
- (vi) it is not a substitute for a product that is a therapy for a disease;
- (vii) it does not augment a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;
- (viii) it does not have a role in the body's response to a disease or to a vector of disease;
- (ix) it does not treat, prevent, or mitigate adverse events associated with a therapy for a disease;
- and
- (x) it does not otherwise suggest an effect on a disease or diseases.

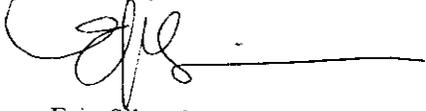
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As written, the claim simply defines chronic inflammation in physiological terms then states general principles one can follow to support good health. The text goes on to list and describe the various ingredients in the product without implication to any effect on inflammation.

We intend to distribute the product that is the subject of the McLind Corporation April 12, 2007 letter with the modified claim described above. Please contact me if I may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'ES', followed by a horizontal line extending to the right.

Erin Silva, MS, RD, CNSD
Technical Marketing Manager
Vitamer Labs
46 Corporate Park, Suite 100
Irvine, CA 92606