

AUG 20 1997

Ms. Lori Akian
Technical Nutrition Assistant
Vitamer
Division of Anabolic, Inc.
17802 Gillette Avenue
Irvine, California 92614

Dear Ms. Akian:

This is in response to your letter of August 8, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for Dong quai powdered extract:

Supports women's health....Dong quai, also known as Dang gui, is an all-purpose herb promoting gynecologic health. Herbalists use this product for PMS, promoting normal menstruation, and for menopausal support;

and the following statement for cayenne powdered extract;

Supports circulatory & digestive systems....Cayenne works synergistically with many herbs by promoting their circulation throughout the body. It also supports digestion and provides nutritional support for the discomforts associated with the common cold.

Section 403(r)(6) of the act 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 or mitigate a disease, in that they are intended to treat or mitigate PMS and the common cold. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 68

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Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

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

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

VITAMER

MAKING
YOUR
NAME

August 8, 1997

Elizabeth Yetley, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SW
(HFS-450)
Washington, D.C. 20204

RECEIVED
8/13/97

Dear Dr. Yetley:

This letter is to notify you that we are offering for sale Cayenne powdered extract as a dietary supplement. It contains the following structure/function statement: Supports circulatory & digestive systems....Cayenne works synergistically with many herbs by promoting their circulation throughout the body. It also supports digestion and provides nutritional support for the discomforts associated with the common cold.

Our label contains the proper disclaimer as well.

Thank you,



Lori Akian
Technical Nutrition Assistant

:lac068.972

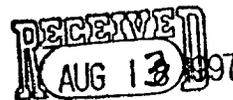
54181

VITAMER

MAKING
YOUR
NAME

August 8, 1997

Elizabeth Yetley, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SW
(HFS-450)
Washington, D.C. 20204



Dear Dr. Yetley:

This letter is to notify you that we are offering for sale Dong quai powdered extract as a dietary supplement. It contains the following structure/function statement: Supports women's health....Dong quai, also known as Dang gui, is an all-purpose herb promoting gynecologic health. Herbalists use this product for PMS, promoting normal menstruation, and for menopausal support.

Our label contains the proper disclaimer as well.

Thank you,

A handwritten signature in black ink, appearing to read "Lori Akian".

Lori Akian
Technical Nutrition Assistant

:lac068.976

5/4/87