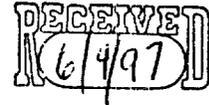




901 E. 233rd Street
Carson, California
90745-6204
310/835-8400
Fax 310/835-6615

May 27, 1997

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



0164 '97 SEP 19 P1:45

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **LEINER HEALTH PRODUCTS** notifies the FDA that it has begun using the following phrase and statements:

In addition, ginseng has been included because it has long been thought of as an adaptogen that promotes energy and stamina.

(Multi-Vitamin and Minerals) The minerals in this formula are helpful for a healthy nervous system and a healthy heart.

(Multi-Vitamin and Minerals) Selenium has been the subject of important recent research, indicating many promising health benefits.

(Calcium) It also helps maintain a healthy heart.

(Siberian Ginseng) This herb has been used for thousands of years as a promoter of good health. Ancient cultures have placed high value on Siberian ginseng and it has long been thought of as promoting energy and stamina.

(Cardio Complex) Uniquely combines vitamin E, which has a positive effect on cardiovascular health, and folic acid, vitamin B₁₂ and vitamin B₆, which have been shown to help maintain healthy levels of blood homocysteine.

975-0162

LET 670

Office of Special Nutritionals (HFS-450)

May 27, 1997

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The above statements are being made on the following product:

Nature's Code™ For Men Under 50

Very truly yours,

LEINER HEALTH PRODUCTS

A handwritten signature in cursive script, appearing to read "Gale Bensussen", is written over a horizontal line.

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Regulatory Affairs