



November 19, 2004

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

NOV 23 2004

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 statement:

Maximum Men's™ is a specially formulated multi-vitamin and mineral supplement designed to help meet the nutritional needs of today's man. Maximum Men's™ formula contains important vitamins, minerals and herbs such as: Vitamin C, which helps boost the immune system, helps keep healthy cholesterol levels, and produces collagen critical for healthy cardiovascular function. Vitamin E, which is a powerful antioxidant that contributes to cardiovascular, mental and prostate health. Korean Ginseng and Damiana, which have been used as a tonic and an aphrodisiac to stimulate libido. Saw Palmetto, which helps maintain prostate health. Vitamin K, which is essential to proper blood clotting. B-vitamins, which work together to help convert food into energy and to help support a healthy nervous system. Beta Carotene, which the body converts into vitamin A that helps support healthy eyes, skin, and immune system. Zinc, which is required for normal healthy skin and hair. Biotin, which is important in fat metabolism. Copper, which aids in formation of red blood cells and is part of cellular energy.

on the following product:

Your Life® Maximum Men's Multi with Herbs

Very truly yours,

Leiner Health Products

Kristi Ansnes
Regulatory Affairs Associate

97S 0162

LET 14965



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Food and Drug Administration
(Continued)

The following brands also use the above statement:

Albertson's
BI-MART
BIO BALANCE®
COUNCIL LABS®
CVS®
ECKERD®
equate®
Hannaford®
HealthLine
health PRIDE
Kash n' Karry
KIRKLAND Signature™
Kroger®
Longs
MARC'S
Member's Mark
MEIJER™

Nature's Origin®
NATURE'S VALLEY™
NATURITE®
NUTRA CHOICE
NUTRI-BLEND
Oscor®
PHARMACIST FORMULA®
BODYCOLOGY™
SAFEWAY SELECT™
Sav•on™
Shaw's
ShopKo®
Spring Valley®
TARGET®
TOP CARE®
TRUNATURE®
Wegmans®