



HVL
Incorporated

600 Boyce Road • Pittsburgh PA 15205-9010 USA • Phone: (412) 494-0100 FAX: (412) 494-0155

Manufacturers and Distributors of Quality Nutritional Supplements for Over 40 Years

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS

'96 JUL 17 A9:34

July 8, 1996

Dr. Elizabeth Yetley,
Director, Office of Special Nutritionals
Food & Drug Administration
200 C Street NW
Washington DC 20204

Dear Dr. Yetley:

Enclosed you will find HVL Incorporated's submission of seven structure-function claims for notification. These claims will be printed no earlier than 40 days from today on the labels for the products which contain these ingredients. These claims also specifically correlate with the substantiation which we hold in our office. Every claim will be followed by the bold disclaimer which will be placed adjacent to the claim.

If you have any questions or comments, please contact Amy Abbato (412)494-0100 directly.

Thank you for your consideration and attention.

Sincerely,

L. Douglas Lioon

President, HVL Inc.

Enclosures: 7

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Chromium naturally assists the regulation of insulin which normalizes blood sugar levels and also helps the body to better metabolize lipids. This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

GLA (gamma linoleic acid) is an omega 6 fatty acid which the body can not produce itself. It helps to regulate saturated fats and cholesterol levels. GLA has also been found to help alleviate the symptoms of premenstrual syndrome. This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Glucosamine Sulfate promotes the natural production of cartilage and is a beneficial supplement for maintaining and restoring the integrity of healthy joints. This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Lipoic Acid (Thioctic Acid) protects against damage to the cells caused by oxidative stress and free radicals. This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Phosphatidylserine is a naturally occurring phospholipid nutrient which can help improve memory impairment and cognitive function. This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Primrose oil is a rich source of GLA, an omega 6 fatty acid the body does not produce itself, which helps to regulate saturated fats and cholesterol levels. Primrose has also been found to help alleviate symptoms of premenstrual syndrome. This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

URO PRO contains a special blend of nutrients including Saw Palmetto and Pygeum Africanum, rich sources of free fatty acids and phytosterols, which inhibit the multiplication of prostate cells and swelling. This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.