



HVL
Incorporated

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Manufacturers and Distributors of Quality Nutritional Supplements for Over 40 Years

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OFFICE OF SPECIAL
NUTRITIONAL SUPPLEMENTS - 450

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December 11, 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 six 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 ext. 712 directly.

Thank you for your consideration and attention.

Sincerely,

L. Douglas Lion

President, HVL Inc.

Enclosures

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Unijoint is a combination of natural ingredients, including glucosamine sulfate, which is specifically designed to ease discomfort and inflammation while 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.**

Vitamin E is an important antioxidant which assists the body's defense against cell damage by neutralizing free radicals and inhibits high levels of LDL (low density lipoprotein) cholesterol. **This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.**

Garlic, or *allium sativum*, is an important herb that has been noted for its health benefits for centuries. Garlic contains an active ingredient called *allicin* which naturally lowers cholesterol levels. **This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.**

Natursyl is a unique blend of ingredients including citrus pectin and psyllium seed, intended to naturally stimulate the bowel. Natursyl also provides acidophilus and bifidus which are friendly flora responsible for keeping a healthy balance in the intestines. **This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.**

Ginkgo Biloba is an herb which contains an active ingredient called *ginkgo flavoglycosides* which protects the body against damage from free radicals and also improves mental performance and circulation. **This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.**

Cal5 + Mg is a special chelate complex of 5 sources of phosphorus-free calcium with Magnesium and other ingredients to assist the body in maintaining healthy bones. Calcium is a primary mineral for building strong bones and teeth. **This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.**