

AUG - 5 1996

Mr. L. Douglas Lioon
President
HVL Incorporated
600 Boyce Road
Pittsburgh, Pennsylvania 15205-9010

Dear Mr. Lioon:

This is in response to your letter of July 8, 1996 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 statements on the labels of your products:

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.

Glucosamine Sulfate promotes the natural production of cartilage and is a beneficial supplement for maintaining and restoring the integrity of healthy joints.

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.

We would point out that 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 for one of these purposes, in that: (1) GLA (gamma linoleic acid) and (2) Primrose oil claims to alleviate the symptoms of premenstrual syndrome and (3) Glucosamine Sulfate claims to be beneficial for restoring the integrity of healthy joints. These claims on the label or in the labeling of these products evidence that they are intended to treat, or mitigate disease and that the products 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

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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, Philadelphia District Office, Office of Compliance, HFR-MA100

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