

MAR - 6 1996

Jonathan W. Emord
Emord & Associates, P.C.
1050 Seventeenth Street, NW, Suite 600
Washington, D.C. 20036

Dear Mr. Emord:

This is in response to your letter of January 6, 1996 making a submission 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 statement of nutritional support for the product "Folic Rinse."

In solution form, folic acid nutritionally supports the health of gingival tissue. Locally applied folic acid solution promotes healthy tissue by reducing gingival exudate from gums. Folic Rinse provides optimal nutritional support for gingival health.

This product does not appear to meet the definition of a dietary supplement in 201(ff)(2)(A)(i) of the act, which states that the term "dietary supplement" means a product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form. This product is not intended for ingestion, but is intended to be used as a rinse for the mouth. Furthermore, it appears that this product is intended for drug use within the meaning of section 201(g)(1) 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.

Sincerely yours,

John Gordon
Acting Director,
Division of Program 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, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement,
HFC-200

975-0163

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formation of skin and digestive tissues. *Niacitol is well tolerated and is unlikely to cause flushing, a common side effect of niacin.*

[See Exhibit 15 for supporting documentation]

Taurine

Taurine is the most abundant free amino acid in the brain, heart, gallbladder, eyes, and vascular system. It facilitates the passage of sodium, potassium, and, possibly, calcium and magnesium ions into and out of cells, and electrically stabilizes cell membranes. It modulates the activity of cAMP, which activates important enzymes in heart muscle, and contributes to the muscle's contractibility. Taurine is an important component of bile acids which aid in the absorption of fat soluble vitamins. It aids the body's chemistry by detoxifying harmful chemicals. Dietary taurine stimulates the formation of taurocholate, a substance which increases cholesterol secretion in the bile and also improves fat metabolism in the liver. *Taurine offers a wide range of nutritional support to many organ systems throughout the body; as a supplement it is not notably known for its heart muscle support.*

[See Exhibit 16 for supporting documentation]

Vitamin A

Vitamin A is essential to the proper functioning of a number of biological processes. It supports vision, growth, reproductive function, the body's defense system, and proper maintenance of skin and mucous membranes. *Vitamin A provides a wide range of nutritional support for the entire body system, including the body's defense system.*

[See Exhibit 17 for supporting documentation]

Iron-C

The major function of iron is to combine protein and copper in the synthesis of hemoglobin. Iron is necessary to manufacture myoglobin, a transporter of oxygen found in muscle tissue which causes the chemical reactions that initiate muscle contractions. Vitamin C enhances the intestinal absorption of iron. *Iron-C provides the body with a highly utilizable form of iron, supporting optimal muscle function.*

[See Exhibit 18 for supporting documentation]

Folic Rinse

In solution form, folic acid nutritionally supports the health of gingival tissue. Locally applied folic acid solution promotes healthy tissue by reducing gingival exudate from

gums. *Folic Rinse provides optimal nutritional support for gingival health.*

[See Exhibit 19 for supporting documentation]

Folate

Folate functions with vitamin B12 and ascorbic acid in the breakdown and utilization of proteins. It is necessary for the growth and reproduction of red and white blood cells, the formation of nucleic acids, the conversion of homocysteine to methionine, and the production of gastric HCl. *Folate provides optimal nutritional support for the proper utilization of proteins and for healthy blood cells.*

[See Exhibit 20 for supporting documentation]

Essential Fatty Acids

There is a growing, cultural trend to eliminate all dietary fat. However, a certain type of fat is actually vital to good health. Essential fatty acids, such as gamma linoleic acid (GLA) and omega-3 fatty acids, support a wide range of physiological functions. GLA supports the body's production of prostaglandin E1 (PGE1). Omega-3 fatty acids increase the formation of prostaglandin E3. These fatty acids are considered essential because they cannot be manufactured by the body, but must come from dietary sources or supplementation. Unfortunately, modern processing techniques remove many of these essential oils from foods.

[See Exhibit 21 for supporting documentation]

Black Currant Seed Oil

Black currant seed oil contains 17% GLA, which is present in only a few other plant seeds.

[See Exhibit 21 for supporting documentation]

Borage Oil

Borage oil contains 24-27% GLA, the highest percent GLA of any plant source.

[See Exhibit 21 for supporting documentation]

E.P.O. (evening primrose oil)

Evening primrose oil has been used in Europe since the seventeenth century and by the Native American Indians for centuries as nutritional support for a wide range of physiological functions. It contains 9-12% GLA.

[See Exhibit 21 for supporting documentation]

Flax/Borage Oil (organic)

Flax seed and borage oils are both effective dietary aids. Flax seed oil contains 55-75% omega-3, and borage oil contains 24-27% GLA. Because this combination