



The Vitamin Marketing Experts

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March 10, 1998

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING GINGER. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING GINGER was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"Ginger soothes and improves digestive function."

Ginger (latin name: *zingiber officinale*), is the root of a tropical plant valued throughout the world for over 2,500 years as a spice. The ancient Greeks and Romans ate *Ginger* for its soothing effect on digestion after meals.

Today, recent studies identify *Gingerols*, compounds that give *Ginger* its strong aroma, as the principle active ingredients for *Ginger's* well known benefits as a digestive aid. Family Essentials for the Mature Woman contains *Ginger* that is standardized using the *Gingerols* content most often used in scientific studies. Further research also shows that *Ginger* can help soothe an unsettled stomach as a result of traveling.

Very truly yours,
MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs

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STUDIES FOR GINGER CLAIMS

Mowrey DB, Clayson DE., "Motion Sickness, *Ginger* and Psychophysics" *Lancet*; 1982, 20:1 (8273), 665, 1982.

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Fuchs, U., "Antiemetic Substances from *Magnolia oibvata* and *Zingiber officinale*" *Z. Phytother.* 15/4, 231, 1994.

Renovanz KD, "Double-Blinded trial with two forms of bromhexine linctus" *Therapiewoche*; 24(41) 4664-4650, 1974.

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Srivastava K., *Prost. Leukotri Med.*; 13:227-235, 1984.

"Effects of *Ginger* on Motion Sickness Susceptibility and Gastric Function" Stewart, John J., Wood, Wood & Mims Louisiana State University Medical Center, Shreveport, LA *Pharmacology* 1991; 42:111-120