



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 CHASTE BERRY (VITEX). FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING CHASTE BERRY (VITEX) was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"Chaste Berry (Vitex) helps in lessening the discomfort associated with menopausal changes"

"Chaste Berry (Vitex) has long been used to ease a woman's monthly cycle for overall comfort and balance".

"Chaste Berry (Vitex) through its hormone balancing effect, has been one of the most successful herbal extracts used by young and adult women to help lessen monthly discomfort"

The *Chaste Berry* herb (latin name: vitex agnus castus) is the aromatic fruit of a small tree with slender violet flowers that typically grows in the Mediterranean and Central Asia. Europeans have long used *Chaste Berry* for its beneficial effects on a woman's menstrual cycle.

Family Essentials™ New Woman™ contains *Chaste Berry* that is standardized using one of its flavonoids, agnuside. Numerous studies with women have shown that *Chaste Berry* helps reduce blood levels of a hormone called prolactin. Elevated blood levels of prolactin are associated with premenstrual discomfort.

Very truly yours,
MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs

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March 10, 1998

Page 2

STUDIES FOR CHASTE BERRY (VITEX) CLAIMS

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