

The sensi bl eway to get your EFAs

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March 23, 2001

Food and Drug Administration Office of Special **Nutritionals** (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sir or Madam,

Notice is hereby given pursuant to the requirement of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that EFAsense Ltd., 5 Crescent Hill Drive South, Brampton, ON L6S 2P2 within the past 30 days commenced marketing dietary supplements bearing the following statement(s) on the label and/or in the labeling:

Text of Claim: The natural choice for PMS. Premenefa™ is a unique, clinically tested formula for premenstrual syndrome (PMS) for which there is a patent pending. Premenefa™ is a synergistic blend of essential fatty acids from borage and flax oils, along with bioflavonoids, cramp bark, chaste berry and vitamin E. This formula is designed to help maintain hormonal balance throughout the month. A placebo-controlled clinical trial showed that **Premenefa™** may alleviate minor PMS symptoms such as cramping, breast tenderness, bloating, minor mood swings, irritability; low energy, lack of concentration, fatigue, and cravings. On average, symptoms were reduced 67% after 3 months of supplementation.

Name of ingredient(s) that is subject of claim: Borage Seed Oil, Flax Seed Oil, Cramp Bark Extract, Bioflavonoids, Chaste Berry Fruit Extract, Vitamin E

Name of supplement (including brand name): EFAsense™ Premenefa™

The undersigned certifies that the information contained in this notice is complete and accurate and that EFAsense Ltd. has substantiation that the statement is truthful and not misleading.

Sincerely,

Joe Vidal Director

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