

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA and 21 C.F.R. § 101.93

RECEIVED
9/23/03

This notification is being filed on behalf of Se-cure Pharmaceuticals Ltd. which is the producer of the **dietary supplement product** which bears the statements identified in this notification. Its business address is: P.O.Box 299, Ben Gurion Airport 70100, Israel. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is Femarelle™.

A. The text of each structure-function statement for which notification is now being given is:

(Statement 1): Provided fast acting relief of menopausal symptoms (ave. 5-7 days).

(Statement 2): Alleviated menopausal symptoms in 3 out of 4 patients.

(Statement 3): Relieved hot flashes in 76% of patients.

(Statement 4): Improved headaches in 68% of patients.

(Statement 5): Improved joint and muscle discomfort in 70% of patients.

(Statement 6): Studies have shown that Femarelle™ promoted bone health.

(Statement 7): Increased Bone Mineral Density.

(Statement 8): For menopausal symptoms and bone health.

(Statement 9): The results of the study showed that Femarelle™ increased Bone Mineral Density (BMD) by: 4.2 % in the spine following 12 months of use.
2.6 % in the hip following 12 months of use.

(Statement 10): Contributing to my future bone health.

(Statement 11): Coping effectively with menopausal symptoms.

(Statement 12): Studies have shown that Femarelle™ stimulates estrogen receptors only at specific tissues, alleviating menopausal symptoms and increasing bone mineral density while having no effect on the uterus and on the breast tissue.

(Statement 13): A clinically proven solution for menopausal symptoms and bone health.

(Statement 14): Had a positive effect on all 15 parameters of the Kupperman index.

(Statement 15): Recommended for women who are suffering from menopausal symptoms such as hot flashes, night sweats, headaches, slight joint and muscle discomfort, and for those who care for the future of their bone health.

(Statement 16): Studies have shown that Femarelle™ alleviates menopausal symptoms such as hot flashes, sleep disturbances, night sweats, and joint and muscle discomfort.

(Statement 17): Furthermore Femarelle™ increases bone mineral density, helping you to maintain bone health.

(Statement 18): The PhytoSERM solution for the relief of menopausal symptoms and bone health.

(Statement 19): Reducing menopausal symptoms.

All statements have been **marked with an asterisk** and the following disclaimer was included wherever a claim was made.

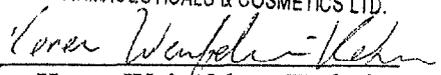
*** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

| <u>Statement Number</u> | <u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u> |
|-------------------------|---|
| 1-19 | Femarelle™ |

I, Keren Weissfelner-Kedmi, am authorized to certify this Notification on behalf of Se-cure Pharmaceuticals Ltd. I certify that the information presented and contained in this Notification is complete and accurate; that Se-cure Pharmaceuticals Ltd. has **adequate scientific** substantiation for each structure-function **claim**; and that each statement is truthful and not misleading.

Date Signed: September 14, 2003

SE-CURE
PHARMACEUTICALS & COSMETICS LTD.

By: Keren Weissfelner-Kedmi
Legal Counsel