



Melaleuca, Inc.

3910 South Yellowstone Hwy
Idaho Falls, Idaho 83402-6003
208 522-0700

6268 '98 SEP 21 P1 52

9/10/98

61091

August 20, 1998

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

Re: SECTION 403(r)(6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Melaleuca, Inc., notifies FDA that it has begun using the following statements:

- Natural support for menopause.
- EstrAval is a natural alternative providing nutritional support for a woman's changing needs throughout menopause. Highest-quality standardized extracts of soy, black cohosh, and dong quai provide an effective combination of phytoestrogens to help maintain a woman's health and well-being during and after menopause.
- EstrAval, a natural support during menopause, delivers compounds similar to the body's own estrogen, and consequently helps maintain a sense of balance and equilibrium to a woman going through menopause. With a unique formulation consisting of natural extracts of soybean, black cohosh, and dong quai, EstrAval gives a woman's body the tools it needs to sustain health and well-being through this natural change.
- The soybean is rich in a unique group of phytoestrogens called isoflavones. These isoflavones appear to be the reason for soy's beneficial effects during menopause.
- Isoflavones look similar to estrogen, and they also act similar, in a way. Because of this similarity, they can "link up" with estrogen receptors, then mimic the actions of estrogen to help maintain the normal function of female body systems.
- Several studies have shown soy's natural health benefits for menopausal women. One study showed that women who consumed isoflavones demonstrated signs of enhanced estrogenic activity. In another 18-week study 43 menopausal women reported significant health maintenance benefits when taking soy. Other studies--as well as surveys of Japanese women (who consume large amounts of soy)--have continually and consistently shown the positive effects of the soybean in maintaining the normal function of the female body systems.
- Clinical studies, as well, have shown black cohosh to help maintain positive body equilibrium during and after menopause.

97S - 0162

LET 2105

Office of Special Nutritionals

August 27, 1998

Page 2

- Dong quai, also known as the "Chinese angelica" in China, is another herb that has long been used during menopause. A tall plant with celery-like leaves and white green flowers, dong quai has been found in animal studies to have estrogen-like effects, and help maintain well-being during menopause.
- EstrAval helps the body maintain a normal, healthy function both before and after the actual menopause occurs.

These statements contain the statutory disclaimer. The name of the dietary supplement is EstrAval™, and the relevant dietary ingredients are Soy extract, Black Cohosh extract and Dong Quai extract.

I certify that the foregoing is complete and accurate, and that Melaleuca, Inc., has substantiation that the statements are truthful and not misleading.

Very truly yours,

Melaleuca, Inc.



McKay Christensen
Chief Operating Officer