



Melaleuca, Inc.

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August 27, 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:

- Promotes emotional health and well-being.
- Luminex is a natural alternative for promoting emotional health, enhanced mood and general well-being.
- Luminex is a dietary supplement specifically formulated to help maintain emotional health.
- Luminex works with the brain's own natural systems to help sustain a strong sense of well-being.
- Researchers have found nutritional compounds--prevalent in the ingredients in Luminex--that help maintain the health and levels of these brain messengers, thus supporting our efforts to deal with our fast-paced lives and with the many events that can throw us off balance.
- St. John's wort's most common use has been to sustain emotional health.
- Hypericin naturally supports the levels of mood-regulating neurotransmitters, helping to maintain positive mood feelings and the ability to cope with stress.
- Though St. John's wort has been used for centuries for mood-enhancing purposes, only recently has it been sent to the scientific laboratory where researchers have looked for proof of its abilities. In the combined results of 23 studies, it showed the ability to support a positive emotional outlook.
- Researchers have found that 5-HTP may possess abilities to maintain healthy neurotransmitters in the brain. It has shown, in studies, to help naturally promote normal levels of certain neurotransmitters, sustaining positive mood and emotional outlook.
- Numerous studies have been performed on 5-HTP, confirming its effectiveness in maintaining emotional well-being.
- While 5-HTP (Griffonia Seed) helps promote normal levels of mood-enhancing

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Office of Special Nutritionals

August 27, 1998

Page 2

neurotransmitters, St. John's wort helps maintain those levels in the brain. Consequently, both extracts working together create a greater effect than either would alone. Accompanied by folic acid and vitamin B12--both of which provide crucial nutrients to assist in normal function of neurotransmitters--these four ingredients combine in Luminex to deliver a broad spectrum of support for good mood and emotional stability.

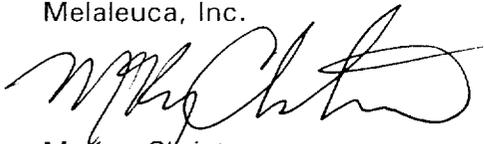
- Researchers have discovered that these B vitamins [Folic Acid & Vitamin B12] are able to supply neurotransmitters with a major component (*S-adenosyl-methionine*) that assists in their normal function. In other words, they naturally support the activities of brain messengers, providing additional maintenance with the nutrients necessary for healthy operation. Evidence of this was found in studies that showed folic acid supplementation to help maintain the proper function of neurotransmitters.
- Combined with a balanced diet and consistent exercise, Luminex can provide the body with the tools it needs to maintain our abilities to deal with the stresses and events we have to face.
- Stronger sense of well-being, a healthy feeling of being able to handle whatever life throws your way.
- Shown in clinical studies to support emotional health and positive outlook.
- Provides the body with the tools it needs to deal with stresses and life events.

These statements contain the statutory disclaimer. The name of the dietary supplement is Luminex™, and the relevant dietary ingredients are St. John's Wort Extract, Griffonia Seed (5-HTP) Extract, Folate and Vitamin B12.

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