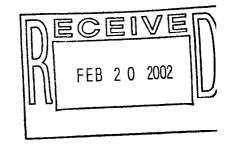


## Melaleuca, Inc.

3910 South Yellowstone Hwy Idaho Falls, Idaho 83402-6003 🔒 2 🛈 208 522-0700

January 29, 2002



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

> **SECTION 403(r)(6) NOTIFICATION** Re:

## 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:

- Restores and tones lean muscle.
- With 20 grams of pure protein per serving, ProFlex20<sup>TM</sup> helps restore, repair, and preserve your muscle tissue.
- Have a shake after a workout to help repair and strengthen muscle tissue, first thing in the morning to get energized and ready for the day, or before bed to prevent overnight protein breakdown.
- It's a great source of leucine, isoleucine, valine, and other vital branch-chain amino acids need for strong muscle tissue.
- Preliminary research shows that whey protein helps lower appetite cravings; enhance bone strength and energy levels; increase blood levels of glutathione, an antioxidant essential to a healthy immune system.
- ProFlex20™ helps restore, repair, and preserve your muscle tissue including your heart.
- Adding whey protein to your diet and exercise routine may help lower appetite cravings and cholesterol; enhance bone strength and energy levels; increase strength and endurance; increase blood levels of glutathione, an antioxidant essential to a healthy immune system.
- ProFlex20<sup>TM</sup>, combined with exercise, helps maintain muscle strength and preserve muscle tone and definition-even in your later years.

79340

Office of Special Nutritionals January 29, 2002 Page 2

- Supplements high in protein, like ProFlex20<sup>TM</sup>, not only repair and enlarge muscle tissue, but extend your energy for a more effective workout. Within weeks you'll notice your muscles growing stronger as you gain more endurance.
- ProFlex20™, combined with a cardio/strength training routine, increases muscle mass and bone density and helps strengthen muscles and bones critical to keeping you young and fit.
- Complete protein for total muscle health.
- It's also an excellent source of leucine, isoleucine, valine, and other branch-chain amino acids needed for the maintenance and repair of muscle tissue. Plus you get important vitamins and minerals, creatine, and natural enzymes, which all work together to help keep you healthy and fit.

These statements contain the statutory disclaimer. The name of the dietary supplement is ProFlex20<sup>TM</sup>, and the relevant dietary ingredients are whey protein, vitamin C, thiamin, riboflavin, vitamin B6, calcium, magnesium, zinc, sodium, potassium, L-glutamine, taurine, creatine monohydrate, papin, and bromelain.

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.

V.P. Product Marketing