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February 25, 2002

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

RECTION				
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BY:				

Dear Sir or Madam:

This notification is being made, as required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, that Inverness Medical, Inc. intends to market dietary supplement products with the following labeling statements of nutritional support:

# Protegra® Cardio

High Potency Heart Support Vitamin & Mineral Supplement

- Homocystine is a substance produced by your body, affecting heart health. Protegra
  Cardio contains all the vitamins you need to break down homocystine levels daily to
  support healthy arteries. It's precisely balanced vitamin and mineral formula also
  supports healthy cholesterol levels.
- Researchers at leading medical institutions have also demonstrated that an intake above the recommended daily values of Folic Acid and Vitamin B6 may help maintain low homocysteine levels.
- Vitamins B6, B12 and Folic Acid break down homocysteine to support healthy arteries.
- And now Protegra Cardio provides Omega-3 fatty acids to promote a healthy blood lipid profile.
- Omega-3 Fatty Acids promote normal triglyceride levels and a healthy blood lipid profile.

### SoyCare® Bone Health

**Dietary Supplement** 

- As you mature, your production of some hormones, including estrogen, slows down.
   Soy Isoflavones are a natural plant hormone (phytoestrogen) that help your body to retain bone mass.
- Isoflavones help you to better incorporate the calcium you take.

978 0162 LET 9596

# Stresstabs® + Iron

**Dietary Supplement** 

- Antioxidant Vitamins C & E: Help protect cells against damage and boost your body's defenses against oxidative stress.
- Folic Acid: Combined with Vitamins B6 and B12 to help maintain normal homocysteine levels in your blood stream.
- Iron: Helps build healthy blood cells that carry oxygen to every cell of your body.

### Stresstabs® + Zinc

**Dietary Supplement** 

- B-Complex Vitamins: Aid in converting food into energy.
- Antioxidant Vitamins C & E: Help protect cells against damage and boost your body's defenses against oxidative stress.
- Folic Acid: Combined with Vitamins B6 and B12 to help maintain normal homocysteine levels in your blood stream.
- Zinc: Assists immune system and overall recuperation.

### Stresstabs®

**Dietary Supplement** 

- Antioxidant Vitamins C & E: Help protect cells against damage and boost your body's defenses against oxidative stress.
- Folic Acid: Combined with Vitamins B6 and B12 to help maintain normal homocysteine levels in your blood stream.

### Ferro Sequels

Iron Supplement

- Delivers iron slowly to maximize absorption, and gently to reduce stomach upset.
- Gentle to your system.

If you have any questions regarding this information please do not hesitate to contact me.

Best regards,

Anna M. Micciulla

Director of Quality Assurance & Regulatory Affairs

Inverness Medical, Inc.