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Ms. Anna M. Micciulla
Director of Quality Assurance & Regulatory Affairs
Inverness Medical, Inc.
51 Sawyer Road
Suite 200
Waltham, Massachusetts 02453

Dear Ms. Micciulla:

This is in response to your letter of February 25, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your letter, you notified us about a claim you intend to use for your dietary supplement **Protegra® Cardio**.

The product **Protegra® Cardio** uses the claim "...supports healthy cholesterol levels." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

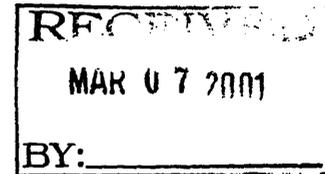
FDA, New England District Office, Office of Compliance, HFR-NE240



79541
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Telephone 781-647-3900
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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



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.

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.
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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.