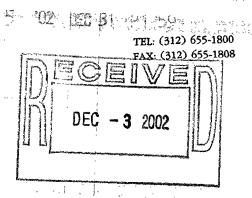
## GRONEK & ARMSTRONG

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DENNIS M. GRONEK ROBERT E. ARMSTRONG PAUL J. WISNIEWSKI DEBORAH L. RUSS JACQUELINE P. KULER

November 27, 2002



Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Pkwy College Park, MD 20740

Re: Notification for Statement on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Innovative Botanical Solutions, Inc., Provo, Utah, a distributor of dietary supplement products. Innovative Botanical Solutions has requested that we notify your Agency on its behalf of the inclusion of statements of nutritional support on its dietary supplement product labels.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Innovative Botanical Solutions has made statements of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for its dietary supplements as follows:

## Product Name

## Label Statement(s)

Calm Stomach

Neutralizes stomach acid. Relieves occasional acid indigestion. Calm Stomach provides natural ingredients selected to neutralize acid, relieve occasional acid indigestion, and improve digestion. Calm Stomach also provides a good source of dietary calcium.

Brain Waves w/Huperzine A and Bacopa

Supports memory and increases alertness.
Supports nerve function. Promotes circulation.
Brain Waves is formulated to benefit brain

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function including both short and long term memory. Ginkgo supports overall blood circulation.

Menopause support. Maintains female hormonebalance. Daily-Menopz is a nutritional supplement providing plant estrogen-like compounds benefiting urinary tract function and hormone support.

Promotes immune defense system. Echinacea promotes the immune defense system and creates a friendly environment for microbiological balance especially during seasonal changes.

Binds to fat and cholesterol in food and prevents absorption. Helps maintain cholesterol levels that are already in the normal range. Fat Binders utilizes plant fibers to bind fat and cholesterol to prevent absorption. This is achieved efficiently by utilizing fat emulsifiers, lecithin and chickweed. Phytosterols block fat absorption sites providing an additional fat eliminating method.

Promotes optimal joint flexibility and mobility. Supports natural processes for relieving minor muscle pain following strenuous exercise or other activity. FlexRelief contains Nexrutine, a natural plant extract found to relieve muscle pain following exercise, and White Willow Bark, a natural source of salicin.

Supports joint health. Glucosamine is a natural compound present in joint cartilage. People who wish to support joint flexibility and strength can benefit greatly from glucosamine.

Supports blood pressure that is already in the normal range. Heart Force BP is a blend of essential and natural ingredients that helps your body maintain blood pressure that is already in to normal range. Heart Force BP provides antioxidants to inhibit cell damage, strengthen blood vessels and support blood flow.

Daily-Menopz

Echinacea

Fat Binders

FlexRelief

Glucosamine

Heart Force BP

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Metabo-Basix

Increases thermogenesis. Boosts metabolism and energy. Reduces appetite.

Soy Isoflavones

... genistein, daidzein and glucitein ... isoflavones benefit circulatory, glandular, and immune systems.

Vari-Less

Supports circulation for vein health, strength, and function. Improves appearance of spider veins. Vari-Less is a unique supplement formulated with standardized herbal extracts and nutrients to support vein health.

The undersigned hereby certifies on behalf of Innovative Botanical Solutions, Inc. that the information contained in this correspondence is complete and accurate.

Sincerely yours,

**GRONEK & ARMSTRONG** 

Robert E. Armstrong

PJW:REA:

pr

CC: Innovative Botanical Solutions, Inc.