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October 15, 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

RECE 2 2002 OCT 9 3 2002 BY:

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)

Age Renew

Full spectrum antioxidant, supports memory function, neutralizes naturally occurring free radical compounds that attack cells throughout the body. Specially formulated to respond to both water and fat soluble membranes including the heart, brain and skin.

Cholesterol-Level

Maintains cholesterol levels that are already in the normal range. Cholesterol-Level is formulated to contain plant extracts, herbs and nutrients to

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maintain cholesterol levels that are already in the normal range in combination with diet and exercise.

Energy Blend

Promotes energy and endurance, provides glandular support for thyroid and adrenal glands. Energy Blend is a unique supplement formulated to provide energy and endurance. Selected herbs nourish the thyroid and adrenal glands, EDS<sup>TM</sup>, a propriety blend of enzymes, increase the release of nutrients trapped in the plant cell walls.

Laxalin

Herbal laxative, encourage intestinal contraction and promote proper waste elimination.

Prosta-Balance

Prostate health. Formulated for men over 40 for prostate health.

SeeBright

Supports eye macular health. Formulated with nutrients and plant antioxidants to provide specific needed eye nutrients. The formula provides high potency levels of lutein for eye macular 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:

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CC: Innovative Botanical Solutions, Inc.