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Office of Nutritional Products, Labeling and  
Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition :20  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Section 403(r)(6) Notification

JUL 18

July 8, 2005

Dear Sir or Madam:

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343 (r)(6), and implementing regulation 21 C.F.R § 101.93, Douglas Laboratories submits this notification that the following statements are included in labeling for the following dietary supplement brand names:

Supplement Name

BroccoSabi

Supplement Ingredients:

Wasabia japonica  
Broccoli Sprout concentrate

Statements of Nutritional Support

A unique combination of true Japanese wasabi with a specially standardized broccoli sprout concentrate to support the body's natural detoxification processes.

Found primarily in cruciferous vegetables, including broccoli and cauliflower, ITCs are recognized for the important roles they play in the body's antioxidant and normal detoxifying processes.

Sulforaphane, an ITC found in broccoli, has been studied for its use in supporting normal detoxification processes and helping to maintain antioxidant protection of the body.

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Evidence indicates that sulforaphane can also play important roles in gastrointestinal health as well as helping to support normal cell growth and division.

Supporting phase II enzymes such as quinone reductase and glutathione S-transferase is a critical part of maintaining normal liver health.

Supplement Name:

NattoSyn

Supplement Ingredients:

Nattokinase  
Hesperidin Methylchalcone  
Pomegranate extract

Statements of Nutritional Support

Designed to provide comprehensive support for circulatory health.

It is important to include nutrients that support the functioning of a healthy circulatory system, including healthy blood flow.

Support for Healthy Blood Flow.

Supports Healthy Veins.

Supports Cardiovascular Health.

Proper regulation of fibrinolysis can help maintain a healthy flow of blood through the vascular system and ensure that the body's major organs are continually supplied by oxygen, nutrients and other necessary products for complete health.

Hesperidin methylchalcone is a methylated derivative of the flavonoid hesperidin. Hesperidin methyl chalcone supports and protects the integrity of the vascular system with particular activity in the capillaries and veins.

Supplement Name:

Alpha-GPC

Supplement Ingredients:

Alpha-glycerophosphocholine

Statements of Nutritional Support

While not a true phospholipid, the body can convert it readily into phosphatidylcholine, the most abundant phospholipid found in the body.

Glycerophosphocholine also plays important roles in the synthesis of acetylcholine and the attachment of phosphatidylcholine to DHA (docosahexaenoic acid, an essential fatty acid).

Human studies indicate that glycerophosphocholine may play important roles in maintaining neurological health.

In middle-aged and elderly adults, glycerophosphocholine supports memory and proper cognitive function.

Supplement Name

A.H.C.C. Plus

Supplement Ingredients

Basidiomycetes mushroom extract

Arabinogalactan

Statements of Nutritional Support

Beta-glucans, amino acids and minerals present in A.H.C.C. may also play an important role in its immune supportive properties.

Scientific research indicates that A.H.C.C. may play an important role in supporting the body's natural defense mechanisms.

Other studies have also demonstrated its important roles in helping support overall immune function, including during times of oxidative stress.

Arabinogalactan is added in this formula for the supportive role it plays in immune health.

Supplement Name

Policosanol

Supplement Ingredients

Policosanol

Statement of Nutritional Support

Studied for the important roles it plays in cardiovascular health, policosanol is increasingly becoming recognized for its use in supporting healthy cholesterol levels already in the normal range.

Supplement Name

7-Keto

Supplement Ingredients

3-acetyl-7-oxo-dehydroepiandrosterone

Statements of Nutritional Support

Studies indicate that 7-Keto may be useful in promoting weight loss without the use of stimulants while following an exercise program and healthful diet.

Research indicates that 7-Keto may play important roles in activating thermogenic enzymes and promoting weight loss in the body.

Several clinical studies have been conducted in healthy overweight adults. In one double-blind, placebo-controlled study, subjects given 200 mg of 7-keto reduced body weight more significantly compared with placebo while maintaining a diet and exercise regimen.

Supplement Name

Estro-Mend

Supplement Ingredients

*Pueraria lobata* (Kudzu, root), Red Clover (flowering tops), Novasoy™ Isoflavone Concentrat, Black Cohosh (root), *Bacopa monnieri* (leaf), Cranberry (fruit), Dong Quai (root), Schisandra (fruit and seeds), Sage (*Salvia officinalis*, leaf), and Hops (aerial parts)

Statements of Nutritional Support

The isoflavone complex of soy, *Pueraria lobata* & red clover, support 2-hydroxylation, glucose utilization and bone health.

Phytoestrogens mimic the functions of estrogens without proliferative actions, and include Black cohosh, and Salvia which support and minimize the changes sometimes experienced during menopause.

Adaptogens with nootropic properties such as Bacopa, Salvia and Schisandra support cognition, memory and the facilitation of learning; functions associated with optimal estrogen function.

This formulation offers support of healthy estrogen function.

Supplement Name

Progesto-Mend

Supplement Ingredients

Rehmannia (root), Bupleurum (root), Passion flower (aerial parts), Peony (root), Coleus forskohlii (root), Dioscorea villosa (root) and chasteberry extract (fruit)

Statements of Nutritional Support

Phytosterones (phytosterols with progesterone-like activity) are provided by Chasteberry and *Dioscorea villosa*, which are able to support the health of progesterone responsive tissues without being chemically converted into progesterone.

The progestogenic herbs, Rehmannia, Bupleurum, and *Coleus forskohlii* all belong to a class of adaptogens that support the proper progesterone producing function of the adrenal glands in both genders.

Herbs which mimic other actions of progesterone (including healthy neurological function) complement the phytosterones and progestogenic herbs.

This formulation offers support of healthy progesterone function.

## Supplement Name

Testo-Gain

## Supplement Ingredients

Asparagus (young shoots), Damiana (leaf), Epimedium (Horny Goat Weed, aerial parts), *Lepidium meyenii* (maca, root), *Mucuna pruriens* (seed), *Tribulus terrestris* (root), *Withania somnifera* (Ashwaganda, root), and *Eleutherococcus senticosus* (root)

## Statements of Nutritional Support

Androgenic adaptogens, which support the proper testosterone producing function of the gonads in both genders, include *Tribulus terrestris* as well as *Withania somnifera*, which maintains healthy gonadotrophic hormone production.

While all phytoandrogens can support healthy sexual function, Epimedium and *Lepidium meyenii*, maintain control over the antiandrogenic affects of glucocorticoids and maintain L-arginine-nitric oxide activity, respectively.

The anabolic function of testosterone is supported with *Eleutherococcus senticosus*, *Lepidium meyenii* and *Mucuna pruriens*.

A synergistic combination of phytoandrogens, androgenic adaptogens and other herbs designed to help promote optimal testosterone function by maintaining the health of testosterone producing glands and by supporting the healthy function of testosterone responsive tissues in men and women.

Supplement Name

Testo-Quench

Supplement Ingredients

Saw Palmetto (berry), Fennel (seed), Urtica dioica (leaf),  
Ocimum sanctum (leaf), Trigonella foenum-graecum (seed)  
and Pygeum africanum (bark)

Statements of Nutritional Support

Holy Basil and Fenugreek both have the ability to maintain  
healthy blood sugar and lipid levels.

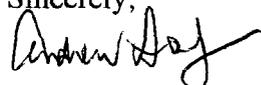
The antioxidant properties observed in each of the herbs may  
also maintain prostate health.

Designed to support the healthy function of testosterone-  
sensitive tissue in women and the health of prostate tissue in  
men.

Douglas Laboratories is the distributor for the dietary supplement. The  
address of Douglas Laboratories is: 600 Boyce Road, Pittsburgh, PA 15205.

I certify that the information contained in this notification is complete and  
accurate and that Douglas Laboratories has substantiation that the foregoing  
statements are truthful and not misleading.

Sincerely,



Andrew Halpner, Ph.D.

Director, Product Development and Technical Services