

November 24, 1998

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

RECEIVED  
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RE: Statements of Nutritional Support – Notification

Dear Sir/Madam:

This letter is submitted by New Vision International, Inc. ("New Vision"), 1920 East Broadway, Tempe Arizona 85282, to notify the agency that pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 343(r)(6), statements of nutritional support are being made for dietary ingredients contained in dietary supplements marketed by New Vision as follows:

1. St. John's+:
  - St. John's Wort has helped millions of people maintain normal and healthy mental function and achieve a more positive outlook.
2. Essential Minerals:
  - And while the body can function without a vitamin, although poorly, we cannot survive without nature's essential minerals - no matter how small their presence in our system.
3. OPC Grape Seed Extract:
  - ...ginkgo biloba extract which provides nutritional support for brain and circulation function,
  - milk thistle to give nutritional support to the liver,
  - bilberry known for its beneficial support to the eyes,
  - along with hawthorn berry - all natural ingredients to help you stay at your mental and physical best.
4. Uña de Gato:
  - Saw palmetto, a traditional herb, has been included because it's believed to support male health and balance.
5. Essential Fatty Acids:
  - Flaxseed oil is nature's richest vegetarian source of Omega-3 and Omega-6 fatty acids. These two acids are important to the health of skin, joints, cell membrane structure and cardiovascular and nervous system.



• 1920 East Broadway  
Tempe, AZ 85282-1702  
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6. FlexRite:

- The primary ingredient in New Vision's FlexRite is naturally occurring glucosamine sulfate. This amazing natural substance... has been shown to support joint health in a large number of clinical studies.
- Glucosamine sulfate promotes the natural production of cartilage and is a beneficial supplement for maintaining the integrity of healthy joints.
- FlexRite not only helps the body stimulate cartilage production, it also promotes joint function.
- ...FlexRite, formulated with glucosamine sulfate, stands ahead of traditional methods by helping your body naturally rebuild connective tissue.
- ...FlexRite naturally promotes cartilage production.
- With FlexRite, the masking of symptoms can be replaced with the improvement of joint health.
- Boswellia extract: Known for its joint health benefits.
- Manganese: Essential trace mineral required for collagen synthesis.
- Vitamin C: Also essential for collagen formation.

7. Neutral C+ CoEnzyme Q10:

- Vitamin C - a nutrient that can only come from our diets - is essential for the formation of body protein and facilitates the building of sound bones, teeth, skin, cartilage and capillaries.
- [CoQ10] As an essential component of mitochondria - the energy producing unit of cells in the body - it is the key to the energy current of all body processes.

8. Imperial Energy:

- This exclusive, all natural, herbal formula was created for one purpose: To help people everywhere feel their absolute best.
- Capturing some of the most highly prized plants in the entire Chinese pharmacopoeia, Imperial Energy balances and harmonizes the major functional energy systems of the body.

9. Essential Botanicals:

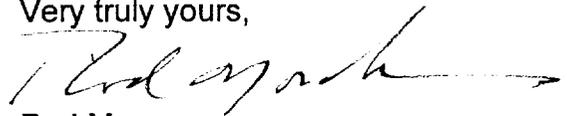
- Ginseng: Helps promote optimal energy.
- Ginkgo Biloba: Supports memory function, mental sharpness and circulation.
- Milk Thistle: Dietary support for the liver.
- Saw Palmetto: Nutritionally supports healthy prostate function.
- Grape Seed: An antioxidant that battles free radicals.

- Echinacea: An herb recognized for its immune support properties.
  - Like a multi, its goal is not to correct or fix a certain condition, but rather to promote overall wellness.
10. Multi-Enzymes:
- Turmeric: Though bland in taste, the root packs a powerful antioxidant punch. Not only does it help the body minimize the cell-damaging ability of free radicals, it also supports digestion by stimulating bile secretion.
  - Cayenne: Sometimes called the "magic" condiment, this herb has been used through the centuries to provide nutritional support for the digestive and circulatory systems.
11. Tract-2:
- Besides offering fiber's myriad of benefits within the gastrointestinal tract, Tract-2 also supports the health of your urinary tract with pure cranberry juice extract - hence the name Tract-2.

The disclaimer required by FFDC § 403(r)(6)(C) accompanies each statement of nutritional support.

The undersigned certifies that the information contained in this notice is complete and accurate, and that New vision has substantiation that each statement of nutritional support is truthful and not misleading.

Very truly yours,



Rod Mora

Senior Vice President of Marketing

RM/pb

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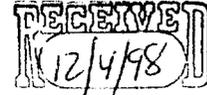


**HEALTHWAY®**

7340 Smoke Ranch Road, Suite D  
Las Vegas, NV 89128

November 24, 1998  
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Via Express Mail



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

Re: Statement of Nutritional Support  
Section 403(r)(6) Notification

Ladies and Gentlemen:

In accordance with the requirements of Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Healthway Corporation, having the address of 1400 Kearns Boulevard, Park City, Utah 84060, notifies the FDA that it has commenced the marketing of the following dietary supplement with the following statement of nutritional support:

<u>Product</u>	<u>Relevant Dietary Ingredients</u>	<u>Statement of Nutritional Support</u>
Ginkgo Complete™	Ginkgo Biloba	To help promote normal blood circulation to the brain.

I certify that the foregoing is complete and accurate, and that Healthway Corporation has substantiation that the statement is truthful and not misleading.

Very truly yours,

HEALTHWAY CORPORATION

By: \_\_\_\_\_

*Nathan Gilliland*  
Nathan Gilliland, Vice President

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Call Toll Free: 877-HLTHWAY

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