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Office of Nutritional' Products, Labeling and Dietary Supplements (HFS-810)

Center for Food Safety and Applied Nutrition Food and Drug, Administration

200 C Street, SW

Washington, DC 20204

Statements of Nutritional Support – Notification

Dear Sir/Madam:

Re:

This letter. is submitted by New Vision International Holdings, 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 a dietary supplement marketed by New Vision as follows:

## hew vision

## Choleste-Care

- Choleste-Care helps your body maintain cholesterol' levels already in the normal range while also protecting against damaging free radical attacks.
- Dan Shen (Red Sage Root) -Used traditionally in Chinese medicine to promote healthy blood circulation.
- Neutral C + CoQ10 Antioxidant vitamin C to support heaithy capillaries plus antioxidant CoQ10 known to assist in cell energy production.
- Super Alo-E Aloe and antioxidant vitamin E help to,promote heart health.
- Essential Minerals Minerals support 'the health of organs such as the heart.
- Contains traditional ingredients, including Mevinolin, which assists your body in maintaining cholesterol levels that are already within the normal range.

1920 E. Broadway
 Tempe, AZ 85282-1702
 T. 480.927.8999

F. 480.927.8665

Teamwork.

Integrity.

Freedom.

97S 0162 LET 7643

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## Cellular DX

- Boosting the body's supply of calcium glucarate may help promote glucuronidation and may help minimize the risks to long-termhealth posed by exposure to toxins.',
- Cellular DX developed by New Vision delivers this crucial nutrient in a unique patented form, Calcium D-Glucarate, and also featurestargeted phyto-antioxidants to protect your cells against damaging free radical attacks.
- © Cellular DX helps your cells to eliminate, toxins, while also protecting against damaging free radical attacks,
- © Calcium D-Glucarate may support one of the body's important detoxification processes: Glucuronidation.
- In this process, glucaric salts inhibit an enzyme that allows toxins to remain in the body. Once this enzyme is blocked, toxins can begin to excrete from the body.
- In support of this detoxification process, Cellular DX also provides plant-derived antioxidants to scavenge damaging free radicals.
- © Citrus **Bioflavonoids**: provide additional cellular antioxidant 'protection.
- The Detox Pack provides nutritional support for health cellular function, with:
- © Cellular DX Features Calcium D-Glucarate to support the body's natural ability to eliminate toxins at the cellular level.
- OPC Grape Seed Extract Concentrated antioxidants fight environmental free radicals that constantly bombard our bodies.
- Calcium **D-Glucarate** can enhance the ability to excrete toxins through the major detoxification pathways in. the **body**.

Office of Nutritional Products, Labeling
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• Cellular DX also provides plant-derived antioxidants such as green tea extract and citrus biaflavonoids to help scavenge damaging free radicals.

The disclaimer required by FFDCA § 403(r)(6) 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,

Lynn McGovern

Senior Director, Marketing

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