



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR 25 2000

Karen A. Weaver
Weaver & Amin
150 N. Wacker Drive
Suite 2020
Chicago, IL 60606

Dear Ms. Weaver:

This is in response to your letter to the Food and Drug Administration (FDA), dated March 15, 2000, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission, on behalf of Healthwatchers System, Inc., states that Healthwatchers System, Inc. is making the following claims, among others, for the following products:

GH3X

"...maintains blood pressure and supports narrowed vessels..."
"Helps enhance healthy blood pressure."

GH3X Booster

"...promoting normal blood clotting..."
"...promotes blood clotting..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate disease, namely coronary heart disease, hypertension, and disorders of platelet aggregation. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 359

Page 2 - Ms. Karen A. Weaver

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copy:

Mr. Gary Martin
President
HealthWatchers System, Inc.
13402 North Scottsdale Road
Suite B-150
Scottsdale, Arizona 85254-4054

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Barnett, Nickerson, Dorsey)
f/t:rjm:HFS-811:4/24/00:70311.adv:disc46

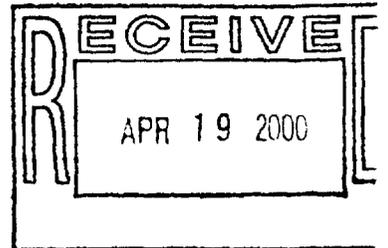
Weaver & Amin
Attorneys at Law

150 N. Wacker Drive
Suite 2020
Chicago, IL 60606
312.701.0844
Fax 312.701.9044
firm@weaveramin.com

Karen A. Weaver, J.D., R.Ph.
Rakesh M. Amin, J.D., R.Ph.
Michael L. Clerkin, J.D., L.L.M.
Charles A. Rego, J.D.

March 15, 2000

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



Re: **Notification of Statements of Nutritional Support**

Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under section 101.93 of 21 Code of Federal Regulations and section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, as Amended.

If necessary, please address future correspondence to our firm.

Very truly yours,

Weaver & Amin

A handwritten signature in cursive script, appearing to read "Karen A. Weaver".

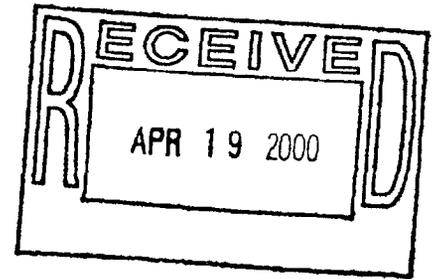
Karen A. Weaver

KAW:kts

Enclosure

70311

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



Re: Statements of Nutritional Support

Dear Sir:

Consider the following as notification of Statements of Nutritional Support as required under Section 403(r)(6) (21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act and in accordance with Section 101.93 of 21 Code of Federal Regulations.

Distributor Name & Address: HealthWatchers System, Inc.
13402 North Scottsdale Road, Suite B-170
Scottsdale, Arizona 85254-4054 ¹⁵⁰

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
"Allows you to stay calmer for longer periods of time"; "Lowers anxiety while encouraging physical activity"; "Help slows down the release of stress hormones which can trigger and raise anxiety levels"; "Encourages more restful sleep"; "Can elevate your moods and feelings of calmness"; "Maintains healthy bones, teeth, and muscles while promoting normal blood clotting and a steady nervous system"; "Helps the body metabolize the carbohydrates needed for healthy brain functioning"; and "Helps promote hormonal secretion, aids in blood formation, promotes blood clotting, and supports the immune system".	Vitamin E, Hypericum, Calcium Chelate, Thiamine Mononitrate Powder, Riboflavin, Beta-Carotene Powder, Zinc (Chelate), Glutathione, Folic Acid, Selenium Chelate, Chromium Polynicotinate	GH3X Booster

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.

A handwritten signature in black ink, appearing to read "Gary Martin".

Gary Martin
President
HealthWatchers System, Inc.

70311

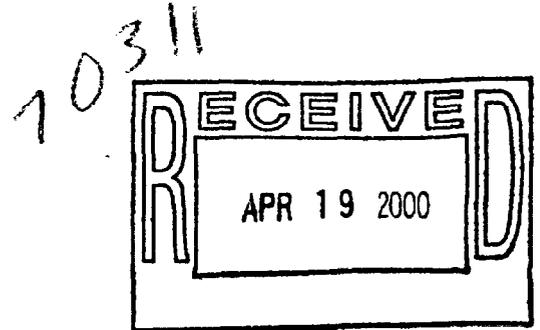
Weaver & Amin
Attorneys at Law

150 N. Wacker Drive
Suite 2020
Chicago, IL 60606
312.701.0844
Fax 312.701.9044
firm@weaveramin.com

Karen A. Weaver, J.D., R.Ph.
Rakesh M. Amin, J.D., R.Ph.
Michael L. Clerkin, J.D., L.L.M.
Charles A. Rego, J.D.

March 15, 2000

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



Re: Notification of Statements of Nutritional Support

Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under section 101.93 of 21 Code of Federal Regulations and section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, as Amended.

If necessary, please address future correspondence to our firm.

Very truly yours,

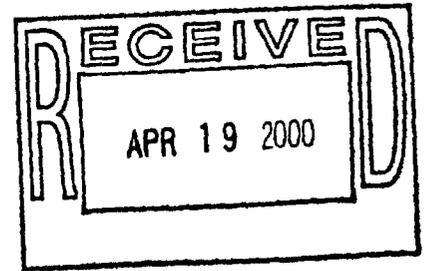
Weaver & Amin

Karen A. Weaver

KAW:kts

Enclosure

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



Re: Statements of Nutritional Support

Dear Sir:

Consider the following as notification of Statements of Nutritional Support as required under Section 403(r)(6) (21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act and in accordance with Section 101.93 of 21 Code of Federal Regulations.

Distributor Name & Address: HealthWatchers System, Inc.
 13402 North Scottsdale Road, Suite B-170^{ISO}
 Scottsdale, Arizona 85254-4054

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
<p>"Helps improve cardiovascular activity, maintains blood pressure and supports narrowed vessels and brain function"; "Helps maintain memory"; "Helps enhance healthy blood pressure"; "Helps maintain respiratory capacity"; "Helps regulate cardiovascular effects"; "Furnishes higher energy"; "Promotes health and vitality"; "Helps promote the normal health and growth of friendly bacteria"; "Aids digestion"; and "Helps alleviate signs of premature aging".</p>	<p>L-Glutamic Acid, L-Tyrosine, 2-Dimethyl Aminoethanol Bitartrate (DMAE), Glucosamine HCl, Para-Amino Benzoic Acid, Choline Bitartrate, L-Taurine, Ascorbyl Palmitate, Magnesium Aspartate, Ginkgo Biloba, Vitamin B6, Vitamin B12, Vitamin E, Acacia Gum, Barley Grass, Bilberry, Cat's Claw, Dulce, Echinacea, Fennel Seed, Fo-Ti, Garlic (Deodorized), Ginger, Ginkgo Biloba, Ginseng, Goldenseal, Irish Moss, Kelp, Licorice, Nettles, Pau D'Arco, Saussurea, Schizandra, Spirulina, Wheatgrass, Apple, Blueberry, Cantaloupe, Cherry, Grape, Grapefruit, Lemon, Orange, Papaya, Peach, Pear, Pineapple, Plum, Raspberry, Strawberry, Watermelon, Beet, Broccoli, Brussel Sprouts, Carrot, Cauliflower, Celery, Kale, Leek, Onion, Radish, Spinach, Sprout, Tomato</p>	<p>GH3X</p>

70311

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.

A handwritten signature in black ink, appearing to read "Gary Martin", written over a horizontal line.

Gary Martin
President
HealthWatchers System, Inc.