



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 22 2000 12 28 6 '00 MAY 25 12:01

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

Dear Ms. Weaver:

This is in response to your letter to the Food and Drug Administration (FDA), dated May 12, 2000. Your letter responds to our April 25, 2000 letter concerning claims being made for products marketed by HealthWatchers System, Inc. pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter contained revisions to claims that were the subject of our previous letter.

FDA appreciates your client's efforts to ensure that statements made on the label and labeling of its products comply with the Act. We have considered the revised claims in your letter and have the following comments. As we stated in our previous letter, 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. FDA believes that statements for a dietary supplement that the product is to "maintain healthy blood pressure" represent that product as being intended to treat, prevent, or mitigate a disease, namely hypertension or other blood pressure disorders¹. Consequently, the claims for the product **GH3X** do not meet the requirements of 21 U.S.C. 343(r)(6). The claim that the product will "maintain healthy blood pressure" suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

We have no further comment on the claims proposed for the product **GH3X**.

¹The basis for our conclusion that this type of claim is an implied disease claim is discussed in the January 6, 2000 Federal Register (65 FR 1000); see discussion for comments 44 and 45 at page 1017.

975-0163

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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
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Barnett, Nickerson, Dorsey)
f/t:rjm:HFS-811:5/19/00:70311b.adv:disc47

Weaver & Amin
Attorneys at Law

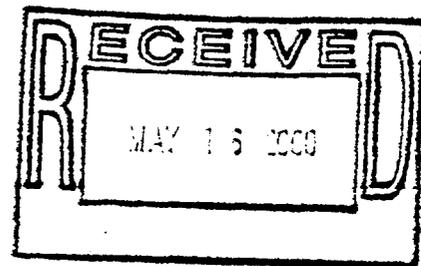
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Of Counsel

May 12, 2000

Mr. John B. Foret
Director, Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, D.C. 20204



Dear Mr. Foret:

This letter replies to your April 25, 2000 communication regarding FDA's allegation that certain statements of nutritional support we filed for our firm's client, HealthWatchers System, Inc. suggest that the associated products are intended to treat, prevent or mitigate disease.

At the outset, we want to assure the FDA that our client places a high priority on compliance with the Federal Food, Drug, and Cosmetic Act and with FDA regulations. While we maintain that the subject statements of nutritional support for our client's GH3X and GH3X Booster dietary supplement products meet the regulatory criteria under the Dietary Supplement Health and Education Act of 1994 and that the claims as currently drafted do not suggest that the products are intended to treat, prevent or mitigate disease, we are willing to make the following revisions to future labeling.

GH3X

Current: "...maintains blood pressure and supports narrowed vessels..."
Proposed: "...helps maintain healthy blood pressure."

Current: "Helps enhance healthy blood pressure."
Proposed: "Helps maintain healthy blood pressure."

GH3X Booster

Current: "...promoting normal blood clotting..."
Proposed: "...contains nutrients essential for the body's normal clotting functions..."

Current: "...promotes blood clotting..."
Proposed: "... contains nutrients essential for the body's normal clotting functions..."

Mr. John B. Foret
U.S. Food and Drug Administration

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Please contact me at the above address if the above-proposed revisions are acceptable to the FDA. If so, our client will institute the revisions to all future labeling.

The foregoing proposal does not constitute an admission by our firm's client that any of its products or labeling violates any applicable statute or regulation.

I look forward to hearing from you and concluding this matter.

Very truly yours,

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

Karen A. Weaver

Cc: client