



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 29 2003

Mr. Lawrence Tabak
Tabak's Health Products
3108 Airport Loop Drive
Suite G
Costa Mesa, California 92626

Dear Mr. Tabak:

This is in response to your letter of June 20, 2003 to the Food and Drug Administration (FDA) 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 states that Tabak's Health Products is making the following claim, among others, for the product HeartShield™ :

“...stave off full-blown high-blood pressure.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely hypertension. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim 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.

Please contact us if you require further assistance.

Sincerely yours,

Susan J. Walker, M.D.

Acting Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

975-0163

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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

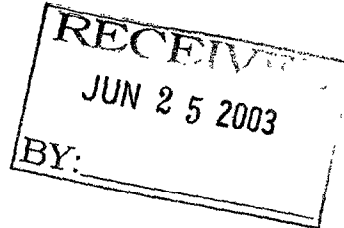
FDA, Los Angeles District Compliance, HFR-PA240

Tabak's
HEALTH PRODUCTS
A Corporation

Our Guiding Philosophy:
Superior, *Science-Based*
Nutritional Supplements

June 20, 2003

Mr. Robert Moore
Food and Drug Administration
5100 Paint Branch Pkwy
Room 4C083
College Park, MD 20740



Dear Mr. Moore,

In compliance with the final ruling for Dietary Supplements dated January 6, 2000 here are copies of our offers for your files:

Sincerely,



Lawrence Tabak

Enclosures

84816



**Our Guiding Philosophy:
Superior, *Science-Based*
Nutritional Supplements**

I, Lawrence Tabak, certify the accuracy of the information presented and contained in the notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

To the best of my knowledge and belief, I believe the above is true.



Lawrence Tabak,
President

HS

Free 30-Day Trial

- CERTIFICATE -

[KEY CODE]
[CUSTOMER#]

[DATE]

No Risk To You
If at any time you would like
postage to respond to this offer or
return product, call 1-800-749-3937
for a postage paid reply label.

[FINDER#]

[Firstname Lastname]
[Street Address]
[City, STATE ZIPCODE]
[Barcode]

[Firstname, sign the back. Correct address if needed.] [Tear Here and Mail Today!]

[Firstname Lastname]
[Street Address]
[City, State Zipcode]
[Barcode]

[Date]

Dear [Firstname],

Tens of millions of Americans went to sleep on Sunday, May 13, 2003 with what they thought was "normal" blood pressure. I was one of them.

On Monday we learned - from our government - that we had something called "prehypertension." And while officials at the National Heart, Lung and Blood Institute were quick to say that

30-DAY FREE TRIAL

Mail To:
Tabak's Health Products
3198 Airport Loop Drive, Suite G
Costa Mesa, CA 92626-3407

YES! I want to keep my heart and "cardio" system as healthy as possible and worry less.

Please rush my **FREE 30-DAY TRIAL**.

If I don't want HeartShield™ for any reason, I'll return the unused portion or empty container to you and owe nothing - no questions asked. But if I decide to keep it, I'll gladly pay the bill of only \$29.97 plus shipping and continue to receive a fresh supply each month. I may cancel future shipments at any time.

(Make Corrections To Your Name or Address on Other Side if Needed)

X

Tear Here and Mail Coupon Today!

Sign name here[, Firstname]

- 2 -

square between the eyes. You realize...

**It's Not Only How Long I Live That's Important...
It's How Well I Live.**

That's the reason you should try HeartShield™ [Firstname].
Because you know good health is worth its weight in gold.

If playing with your grandchildren... enjoying the company of close friends... relaxing with your pet on your lap... are important to you... take action now to maintain your quality of life.

Remember, your hard-working heart has more to do with your well-being than any other part of your body.

Experience HeartShield™ for yourself. Take it for 30 days. If you're thrilled - as I'm sure you will be - pay for it. If not, simply return the empty container. Your bill will be cancelled. No questions asked. And you won't owe a dime.

But I'm betting that won't be the case. I think you'll love HeartShield™ - especially when you see it's loaded with heart