



JAN 14 2003

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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 January 3, 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 claims, among others, for the product **ProstLo™** :

"A prostate that acts up!"

"If you're a man over 40...your prostate's going to go on the fritz"

"...nearly all men will experience some sort of prostate problem as they grow older"

"Typical early signs include: More frequent trips to the john. Greater urgency. Getting up several times at night. 'Dribbling.'"

"...if your prostate stops functioning normally..."

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 this product suggests that it is intended to treat, prevent, or mitigate a disease, namely benign prostatic hypertrophy. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

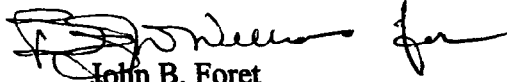
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Please contact us if you require further assistance.

Sincerely yours,



**John B. Foret**

**Director**

**Division of Compliance and Enforcement**

**Office of Nutritional Products, Labeling**

**and Dietary Supplements**

**Center for Food Safety**

**and Applied Nutrition**

**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**

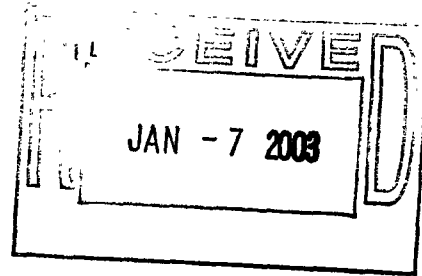
# Tabak's HEALTH PRODUCTS

A Corporation

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

January 3, 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,



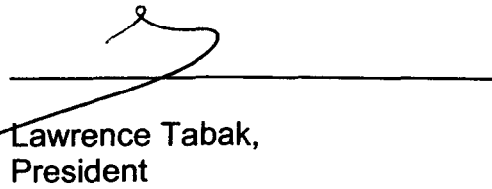
Lawrence Tabak

Enclosures

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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

# Free 30-Day Trial

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.

[DATE]

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

[FINDER#]

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

## The "Secret" to Having Great Sex and Living Longer

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

[MONTH] [DAY], [YEAR]

Dear [Firstname],

Did you know that. . .

### Frequent sex can actually make you live longer?

It sounds odd, I know. But listen to this: A recently published long-term study of 918 men in Wales found those who had at least eight orgasms a month had a 50% better chance of staying alive compared to those who had sex less than once a month.'

So, not only does sex make you feel good, but it's tied to that "life-force" that keeps you vibrant and alive.

Now for the bad news? Your capacity to perform sexually has a silent, deceptive and even ruthless enemy. . .

### A prostate that acts up!

I don't want to scare you. But facts are facts: If you're a man over 40, odds are, at some point, your prostate's going to go on the fritz. In fact, doctors say that nearly all men will experience some sort of prostate problem as they grow older.

How will you know it's happening to you? Typical early signs include: More frequent trips to the john. Greater urgency. Getting up several times at night. "Dribbling."

Why wait until this happens to you [Firstname]?

And it gets even worse. If your prostate stops functioning normally, there's a pretty good chance that. . .

### Your Sex-Life Will Hit the Skids. And Quickly.

And I don't mean "a bit less sex." I'm talking NO sex. Nada. Zero. Nil.

It's a frightening thought, isn't it.

Want some good news now [, Firstname]?

You can help keep your prostate in tip-top condition by giving it a "nutritional tune-up." As part of your healthy diet and exercise

TRIAL OF PROSTLO™ VIA FIRST CLASS MAIL.

If I don't want ProstLo™ 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 \$25.97 plus shipping and continue to receive a fresh supply each month with a bill. I may cancel future shipments at any time.

Mail To:

Tabak's Health Products  
3188 Airport Loop Drive, Suite G  
Costa Mesa, CA 92626-3407

Mail Free Trial Certificate Today!

X \_\_\_\_\_  
Sign name here

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program, take ProstLo™. It contains a special blend of all-natural ingredients proven to maintain a healthy prostate and enhance your natural sexual power.

And here's more good news:

**A Free 30-Day Trial of ProstLo™ is Waiting for You!**

Just tear off your Free Trial Certificate. Sign it. Pop it in the mail. Try it out free - on us - for 30 days. Put this potent prostate enhancer to work for you - with absolutely no risk:

Look. If you're over 40, the chances are better than sixty percent that prostate trouble is in your future. That means[, Firstname]. . .

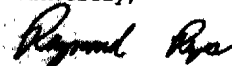
**Doing nothing is a lousy bet!**

Do the smart thing! Do the logical thing. Start nutritionally fortifying your prostate now. It's easy to do. And easy to get started - with your free 30-day trial.

Send for it. Try it for yourself with no risk and no up-front cost. . . then decide. After a month, if you're satisfied, pay the bill that comes with it. If not, simply return the unused portion or empty container. Pay us nothing. Owe us nothing. No questions will be asked. And that will be that.

Any way you look at it, that's "more than fair." So start protecting your prostate and enhancing your sexual energy now. Don't wait.

Sincerely,



Raymond Reyes  
For ProstLo™

P.S. A free 30-day trial of ProstLo™ is waiting for you[, Firstname]. Its ingredients are proven to fortify your prostate and energize your sexual performance. Just tear off your guaranteed "no-risk" certificate. Mail it today!

P.P.S. To ensure your privacy, your 30-day free trial of ProstLo™ will arrive in a plain brown, unmarked package.

Supporting References

1. Dawy Smith G, et al. "Sex and death: are they related? Findings from the Cerepally Cohort Study." British Medical Journal 1997 Dec 20;315(7123):1641-4.
2. Clark LO, et al. "Decreased incidence of prostate cancer with selenium supplementation: results of a double-blind cancer prevention trial." British Journal of Urology 1999 May;81(5):720-4.
3. Farnio MS, et al. "The naturally-occurring alpha-tocopherol inhibitor, reduces rat ventral prostate weight and DNA content affecting histological function." Andrologia 1993 Nov-Dec;25(6):365-71.
4. Gordon GS. "New pathways for the treatment of men with lower urinary tract symptoms." Journal of Urology 2000 May;163(5):1408-17.
5. Wu L, et al. "Chrysin: a natural flavonoid for the treatment of patients with benign prostatic hyperplasia: a systematic review and quantitative meta-analysis." American Journal of Medicine 2002 Dec;113(12):1624-34.
6. Isfahani A, et al. "Efficacy of chrysin for the treatment of patients with benign prostatic hyperplasia: a systematic review and quantitative meta-analysis." American Journal of Medicine 2002 Dec;113(12):1624-34.
7. Kohn E. "Efficacy from trials of oral pantothenic acid (vitamin B5) and (oral) zinc nitrate (vitamin B12) viable alternatives in the medical treatment of benign prostatic hyperplasia and associated lower urinary tract symptoms." Planta Med 2001 Aug;67(8):688-900.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

**Tabak's Health Products**  
Superior, Science-Based Nutritional Supplements  
3188 Airport Loop Drive, Suite G • Costa Mesa, CA 92626

www.tabaks.com