



AUG 12 2002

Rec'd 8/27/02
JB

Ms. Cindy Nydell
Tabak's Health Products
3198 Airport Loop Drive
Suite G
Costa Mesa, CA 92626

Dear Ms. Nydell:

This is in response to your letter of July 24, 2002 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 Glucosamine Sulfate:

"Do You Suffer From Joint Discomfort? Receive a Bottle of Glucosamine Sulfate and "48 Natural Breakthroughs that Relieve Arthritis Pain"..."

"Special report: "48 Natural Breakthroughs That Relieve Arthritis Pain." Which shows you: Seven "must take" nutrients...Four "healthy" foods that arthritis sufferers should avoid like the plague...The three FREE best arthritis pain helpers...Four simple exercises that work wonders...Why Eskimos almost never get arthritis, and what we can learn from them...and much, much more - yours FREE!"

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 in the context of the offer of the "special report," to the extent that the report you are providing to customers describes the benefits of glucosamine sulfate for persons with arthritis, suggest that it is intended to treat, prevent, cure, or mitigate a disease, namely arthritis. 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.

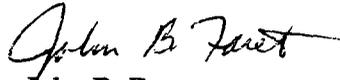
978-0163

LET 633

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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

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, Office of Compliance, HFR-PA240

Tabak's
HEALTH PRODUCTS
A Corporation

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

July 24, 2002

Mr. Robert Moore
Food and Drug Administration
200 C. Street SW
Washington, DC 20204

RECEIVED
AUG 05 2002

BY:.....

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,

Cindy Nydell

Cindy Nydell

Enclosures

81430



**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.

A handwritten signature in black ink, appearing to read "Lawrence Tabak", is written above a horizontal line.

Lawrence Tabak,
President

[CUSTOMER#]

Do You Suffer From Joint Discomfort?
Receive a Bottle of Glucosamine Sulfate and "48 Natural Breakthroughs
that Relieve Arthritis Pain" - a \$30 Value - FREE!!

[KEY CODE]
[FINDER#]

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

[MONTH] [DAY], [YEAR]

Dear [Firstname],

If you'll be kind enough to give me three minutes of your time, I'll repay you with a gift worth \$30 - FREE! Your gift check is enclosed.

Here's what you get:

1) A bottle of Glucosamine Sulfate - an all-natural "joint cushioning" supplement that's been proven to help maintain healthy joint cartilage and provide the natural building blocks your body needs to sustain healthy joint connective tissue - FREE.

2) Special report: "48 Natural Breakthroughs That Relieve Arthritis Pain." Which shows you: Seven "must take" nutrients... Four "healthy" foods that arthritis sufferers should avoid like the plague... The three FREE best arthritis pain helpers... Four simple exercises that work wonders... Why Eskimos almost never get arthritis, and what we can learn from them... and much, much more - yours FREE!

Best of all, I'll rush this \$30 package to your [City] address...

At No Charge to You!

Even the shipping is free! Why am I doing this [Firstname]? Simple. I want to introduce you to some of our natural health products.

Our challenge is matching each product with the right person. So we're trying something really different - that can be of great benefit for you.

If you'll help us, by sharing what health issues matter most to you, we'll send you some of our products to "try" from time to time, on a free trial basis. You're never obligated to buy anything you don't want. Pay only if you decide to keep it. Return anything you wish with our postage-paid label. Therefore, there's absolutely...

No Risk to You!

Simply indicate your preferences on the back of this letter. Sign your name. Pop this letter in the enclosed envelope. Mail it along with your enclosed gift check. And your free gift package - a \$30 value - will be on its way to you!

Just check the boxes that apply to you on the back. Return this letter today.

To Your Good Health,



Veronica Simental

P.S. We've built our company on one premise: That you have to earn a customer's trust before you ask for their business. That's why we offer you a \$30 gift - FREE!. And ask for NO money up front!

(Turn Over Please)

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.

Free Gift Plus No-Risk Preview

Yes, please send my free gift. I've completed your survey below. Based on my answers, send me products to try, from time to time, on a 30-Day Free Trial basis.

If I don't want any product, I'll simply return it and *owe nothing*. No questions asked.

However, if satisfied, I'll gladly pay the bill that comes with it and continue to receive a fresh supply each month with a bill.

I may cancel future shipments at any time. I understand that I can return anything I don't want with your "postage-paid" label at no cost to me. Since there's no risk, I'm going ahead.

Check Only the Boxes that Apply to You

- | | |
|--|--|
| <p style="text-align: center;">Interested
Very Interested</p> <p>1 <input type="checkbox"/> <input type="checkbox"/> Menopause/PMS</p> <p>3 <input type="checkbox"/> <input type="checkbox"/> Maintain cholesterol levels (that are already in the normal range, as part of a healthy diet)</p> <p>4 <input type="checkbox"/> <input type="checkbox"/> Reduce wrinkles/age spot visibility</p> <p>5 <input type="checkbox"/> <input type="checkbox"/> Multi-vitamin for overall health</p> <p>7 <input type="checkbox"/> <input type="checkbox"/> Maintain bowel regularity</p> <p>8 <input type="checkbox"/> <input type="checkbox"/> Joint discomfort (age related)</p> <p>10 <input type="checkbox"/> <input type="checkbox"/> Keep prostate healthy</p> <p>11 <input type="checkbox"/> <input type="checkbox"/> Lose weight</p> <p>12 <input type="checkbox"/> <input type="checkbox"/> Healthy glowing skin with natural mask & cleanser</p> <p>13 <input type="checkbox"/> <input type="checkbox"/> Increase energy</p> <p>14 <input type="checkbox"/> <input type="checkbox"/> Maintain bone density</p> <p>15 <input type="checkbox"/> <input type="checkbox"/> Enhance memory/brain function</p> <p>17 <input type="checkbox"/> <input type="checkbox"/> Blood sugar support (to be used as part of your diet, not intended to affect abnormal blood glucose)</p> | <p style="text-align: center;">Interested
Very Interested</p> <p>18 <input type="checkbox"/> <input type="checkbox"/> Increase sexual energy (age related)</p> <p>19 <input type="checkbox"/> <input type="checkbox"/> Maintain healthy eyesight</p> <p>20 <input type="checkbox"/> <input type="checkbox"/> Keep immune system healthy</p> <p>21 <input type="checkbox"/> <input type="checkbox"/> Serious athlete/improve performance</p> <p>22 <input type="checkbox"/> <input type="checkbox"/> A "lift" from blues/sadness</p> <p>23 <input type="checkbox"/> <input type="checkbox"/> Maintain a healthy heart</p> <p>24 <input type="checkbox"/> <input type="checkbox"/> Leg cramps (night time)</p> <p>25 <input type="checkbox"/> <input type="checkbox"/> Get a good night's sleep</p> <p>26 <input type="checkbox"/> <input type="checkbox"/> Maintain healthy gums</p> <p>27 <input type="checkbox"/> <input type="checkbox"/> Maintain healthy lungs</p> <p>28 <input type="checkbox"/> <input type="checkbox"/> Anti-aging, antioxidant formula</p> <p>29 <input type="checkbox"/> <input type="checkbox"/> Maintain hair fullness/hair health</p> <p>30 <input type="checkbox"/> <input type="checkbox"/> Back and vertebrae health</p> <p>Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female</p> <p>Date of Birth: / /
 Month Day Year</p> |
|--|--|

X

Sign name here

Your email address (optional)

mail to

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

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-800 (r/f, file)

HFS-810 (file)

HFS-811

HFD-40 (Behrman)

HFD-310

HFD-314

HFS-607

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:8/8/02:docname:81430.adv:disc68