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OCT 22 2003

Mr. Ralph Fucetola, J.D.
Attorney at Law
58 Plotts Road
Newton, New Jersey 07860

Dear Mr. Fucetola:

This is in response to your letter of May 9, 2003, on behalf of Peak Health Care Products, Inc., Las Vegas, Nevada, 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 letter submission states that Peak Health Care Products, Inc. is making the following claims, among others, for the product **Yeast Control for Diabetics**:

“Yeast Management Formula For Diabetics”

“...a maintenance product for diabetics who are not presently Candida infected. If you are presently experiencing a yeast flare-up, use Yeasta Way® (9 day or 25 day) cleanse before starting Yeast Control for Diabetics®.”

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 conjunction with the name of the product (i.e., “Yeast Control for Diabetics”), suggests that it is intended to prevent disease (i.e., yeast infections). 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0168

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Page 2 - Mr. Ralph Fucetola, J.D.

You state in your letter that the following disclaimer appears on the product label:

“This product is designed to support the digestion of Candida albicans and other yeasts in the gastrointestinal track [sic] of persons with diabetes. Intended to supplement the nutrient needs of persons with diabetes without affecting the blood sugar or treating diabetes.”

You assert that this disclaimer brings the aforementioned yeast control claims within the scope of claims permitted to be made in the labeling of dietary supplements pursuant to section 403(r)(6) of the Act. We disagree.

Diabetics are known to have a greater risk of yeast infections. The increased risk is believed to be associated with elevations in blood sugar concentration. Your client's product is clearly to prevent yeast infections that are a direct consequence of the person's disease; i.e., diabetes. As such, the product is clearly and unambiguously represented to treat an adverse consequence of a disease (diabetes) that is itself a disease (i.e., yeast infection). Therefore, the claims for your client's product are disease claims within the meaning of 21 U.S.C. 321(g)(1)(B) rather than claims under 21 U.S.C. 343(r)(6). The use of the disclaimer cited in your letter does not change that fact.

Moreover, your reliance on a previous letter from FDA expressing the opinion that certain types of claims about nutritional support for persons with diabetes are structure/function claims is misplaced. In the previous case, FDA conceded that diet restrictions might contribute to nutritional deficiencies in some diabetics and that claims that a product was intended to meet those nutritional needs, rather than any sign or symptom of the disease, may be legitimate structure/function claims. However, the claims being made for this product are, for the most part, not even nominally of the type described in the letter you cited. The current product is not intended to treat any nutrient deficiency associated with the dietary practices of diabetics; rather, it is intended to treat the hallmark symptom of diabetes (i.e., elevated blood sugar levels) in order to prevent a complication of the disease (yeast infection due to elevated blood sugar levels) that is itself a disease. Therefore, the claims being made for this product evidence that it is intended to treat, prevent, cure, or mitigate a disease and is subject to regulation as a drug under the Act.

Page 3 - Mr. Ralph Fucetola, J.D.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Walker".

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copy:

Randy S. Gregg, President
Peak Health Care Products, Inc.
9436 W. Lake Mead Boulevard
#11A
Las Vegas, Nevada 89134

Copies:

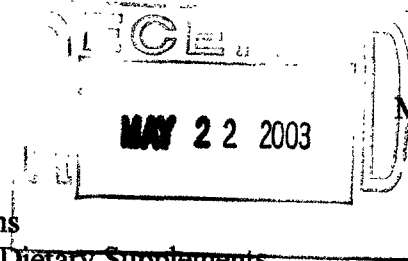
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

RALPH FUCETOLA, J.D.

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www.vitaminlawyer.com



May 9, 2003

The Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
5100 Paint Branch Parkway, College Park, MD 20740-3835 USA

Re: *YEAST CONTROL* For Diabetics™
Structure and Function Claim Notice

Gentlepeople,

I enclose herewith the Structure and Function Claims Notice for the noted product. This product is intended to provide dietary supplementation to persons with diabetes, but not to treat their medical condition. I have therefore patterned the Disclaimer set forth at the end of the list of Claims in the Notice after a product of another client of mine that also offers nutritional support for diabetics.

Robert J. Moore, Ph.D., Chief of the FDA's Division of Compliance and Enforcement wrote to that client on August 21, 2001, "Based on the information in your letter, it appears that the statement you proposed to include in your labeling would adequately address... [our] concerns... The addition of the statement appears to add appropriate context to the labeling to establish that the product is not necessarily intended to treat or mitigate diabetes, but instead is intended to meet specific nutritional needs of persons with diabetes."

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The disclaimer accepted by the FDA, in that case, reads, "Intended to supplement nutrient needs of persons with diabetes, addressing certain nutrient deficiencies found in some diabetics, without affecting the blood sugar or treating diabetes."

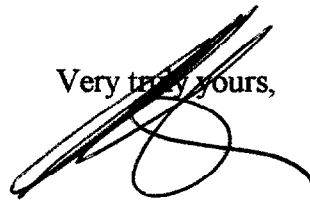
The disclaimer on the Yeast Control product reads,

"This product is designed to support the digestion of *Candida albicans* and other yeasts in the gastrointestinal track of persons with diabetes. Intended to supplement the nutrient needs of persons with diabetes, without affecting the blood sugar or treating diabetes."

I reviewed the substantiation documentation possessed by Peak Health Care Products, Inc. prior to preparing the attached Notice and have advised Mr. Gregg, the Company President, that, in my opinion, he could sign the Notice under the terms of 21 U.S.C. 403(r)(6).

If the Division has any questions regarding this Notice, please let me know.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Ralph Fucetola JD', written over the typed name below.

Ralph Fucetola JD

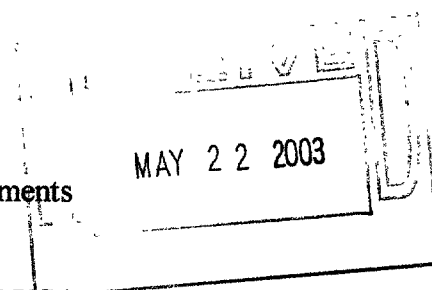
Enc: Notice, Label copy

Cc: R. S. Gregg

**SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA**

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

To: The Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
5100 Paint Branch Parkway, College Park, MD 20740-3835 USA



Date: May ___ 2003.

Re: This Notice covers the following Brand(s): **YEAST CONTROL For Diabetics™**

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s): **Peak Health Care Products, Inc.**

(ii) The text of the statement that is being made: see attached Exhibit A.

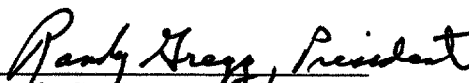
(iii) The name of the dietary ingredient or supplement that is the subject of the statement: see attached Exhibit A.

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001 which makes it a crime to submit false information to the Government.


Randy S. Gregg, President
Peak Health Care Products, Inc.
9436 W. Lake Mead Blvd #11A
Las Vegas, NV 89134
1-866-442-0617

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name(s) Included herein: **YEAST CONTROL For Diabetics™**

2. Dietary Ingredients or Supplements Included herein:

- (a) Cellulase
- (b) Lactobacillus acidophilus
- (c) Lactobacillus rhamnosus
- (d) Lactobacillus casei
- (e) Protease
- (f) Vitamin C
- (g) Apple Pectin
- (h) Gymnema Sylvestre
- (i) Cinnamon

3. Statements Made with regard to each Ingredient:

(a) Cellulase – Supports digestion of cellulose in the gastrointestinal track.

(b) Lactobacillus acidophilus – Promotes bacterial balance in the intestines.

(c) Lactobacillus rhamnosus – Promotes bacterial balance in the intestines.

(d) Lactobacillus casei – Promotes bacterial balance in the intestines.

(e) Protease – Supports digestion of undigested protein and fungal forms.

(f) Vitamin C – Promotes absorption of ingredients into the blood and may help build healthy blood vessel walls.

(g) Apple Pectin – Suppresses appetite, supports normal blood sugar level, supports cholesterol metabolism and regulates enzymatic cholesterol production in the liver.

(h) Gymnema Sylvestre – Supports normal blood sugar level.

(i) Cinnamon – Suppresses appetite, supports normal blood sugar level and supports digestion.

General Claim and Disclaimer on the Label:

This product is designed to support the digestion of *Candida albicans* and other yeasts in the gastrointestinal track of persons with diabetes. Intended to supplement the nutrient needs of persons with diabetes, without affecting the blood sugar or treating diabetes.

Copy of Label attached.

All rights reserved -- UCC 1-207

DIRECTIONS:

Suggested Usage: Two capsules per day for 90 days. One at least one hour before breakfast, and one at bedtime, at least two hours after eating. This product is for both adults and children under adult supervision. Children under 12 - take one capsule daily, at bedtime. Children 12 and over, and adults - take two capsules daily (if you're pregnant or lactating, please consult a health professional about potential interactions before taking this supplement). Yeast Control For Diabetics® is a maintenance product for diabetics who are not presently Candida infected. If you are presently experiencing a yeast flare-up, use Yeasta Way® (9 day or 25 day) cleanse before starting Yeast Control For Diabetics®.

Yeast Control For Diabetics™ is formulated and distributed exclusively by

**Peak Health Care Products
TOLL FREE: 1-866-442-0617**

© Yeast Control For Diabetics™ 2003



YEAST CONTROL FOR DIABETICS

90 day
Maintenance



90 day
Maintenance

**Dietary Supplement
180 Capsules**

Supplement Facts

**Serving Size: 2 Capsules
Servings per Container: 90**

	Amount Per Serving	% DV
Vitamin C (as Ascorbic Acid)	15mg	25%
Apple Pectin	300mg	+
Gymnema Sylvestre Standardized Extract 25% (50mg) Gymnemic Acid	200mg	+
Lactobacillus acidophilus (10 billion CFU**/gram)	150mg	+
Lactobacillus rhamnosus (10 billion CFU**/gram)	150mg	+
Lactobacillus casei (10 billion CFU**/gram)	150mg	+
Cellulase Enzymes (110,000 CU*/gram)	150mg	+
Protease Enzymes	20mg	+
Cinnamon Bark	20mg	+

Other ingredients: Plant Cellulose, Magnesium Stearate, and Silicon Dioxide

+ Daily Value not established

*CU = Cellulase activity

**CFU = Cell forming units

Vegetarian Capsules

**Yeast Management Formula For Diabetics
Certified Laboratory Tested**

Disclaimers & Cautions

This product is designed to support the digestion of candida albicans and other yeasts in the gastrointestinal tract of persons with diabetes. Intended to supplement nutrient needs of persons with diabetes, without affecting the blood sugar or treating diabetes. These statements have not been evaluated by the Food and Drug Administration. Not intended to diagnose, treat, prescribe for, prevent, mitigate or cure any disease or psychological condition. As with all such concerns, you should seek the advice of your physician, if any yeast overgrowth persists or worsens, you should seek a physician's advice immediately. See product label for directions and cautions.
KEEP OUT OF REACH OF CHILDREN Refrigerate After Opening. (Not necessary prior to opening)

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LOT

DIRECTIONS:

Suggested Usage: Two capsules per day for 90 days. One at least one hour before breakfast, and one at bedtime, at least two hours after eating. This product is for both adults and children under adult supervision. Children under 12 - take one capsule daily, at bedtime. Children 12 and over, and adults - take two capsules daily (if you're pregnant or lactating, please consult a health professional about potential interactions before taking this supplement). Yeast Control For Diabetics® is a maintenance product for diabetics who are not presently Candida infected. If you are presently experiencing a yeast flare-up, use Yeasta Way® (9 day or 25 day) cleanse before starting Yeast Control For Diabetics®.

Yeast Control For Diabetics™ is formulated and distributed exclusively by

Peak Health Care Products
TOLL FREE: 1-866-442-0617
© Yeast Control For Diabetics™ 2003



YEAST CONTROL[★]

FOR DIABETICS

90 day
Maintenance



90 day
Maintenance

Dietary Supplement
180 Capsules

Supplement Facts		
Serving Size: 2 Capsules		
Servings per Container: 90		
	Amount Per Serving	% DV
Vitamin C (as Ascorbic Acid)	15mg	25%
Apple Pectin	300mg	+
Gymnema Sylvestre Standardized Extract 25% (50mg) Gymnemic Acid	200mg	+
Lactobacillus acidophilus (10 billion CFU**/gram)	150mg	+
Lactobacillus rhamnosus (10 billion CFU**/gram)	150mg	+
Lactobacillus casei (10 billion CFU**/gram)	150mg	+
Cellulase Enzymes (110,000 CU**/gram)	150mg	+
Protease Enzymes	20mg	+
Cinnamon Bark	20mg	+
Other ingredients: Plant Cellulose, Magnesium Stearate, and Silicon Dioxide		
+ Daily Value not established		
*CU = Cellulase activity **CFU = Cell forming units		

Vegetarian Capsules
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