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Food and Drug Administration
College Park, MD, 20740
AUG 21 05:13

JUL 30 2007

Ms. Patrice B. Hambleton
Konsyl Pharmaceuticals, Inc.
8050 Industrial Park Road
Easton, Maryland 21601

Dear Ms. Hambleton:

This is in response to your letter of July 17, 2007 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 Konsyl Pharmaceuticals, Inc. is making the following claims, among others, for the products:

Bladder Control

“Natural Relief for Incontinence....”

“[D]ecreased frequency of Incontinence....”

“[R]elieve bladder problems...[H]elp reduce incontinence, reduce urinary urgency....”

Lactobacillus Probiotic Complex

“Assist in Restoration after Antibiotic Use.”

Konsyl Balance Natural Psyllium Fiber & Prebiotic Inulin Fiber and Fiberlin Fiber & Antioxidant

“Plant sourced antioxidants...have been found to reduce the risk for chronic diseases.”

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 these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If your client intends to make claims of this nature, they 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.

19975-0163

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Page 2 - Ms. Patrice B. Hambleton

The products **Konsyl Balance Natural Psyllium Fiber & Prebiotic Inulin Fiber (Orange and Wild Berry flavors)** are the subject of claims that represent that it contains soluble fiber from psyllium that may reduce the risk of coronary heart disease. These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B) because they represent that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has authorized a health claim about the relationship between soluble fiber from certain foods and coronary heart disease (see 21 CFR 101.81). A dietary supplement that meets the eligibility and message requirements set forth in the regulation may bear a claim for the relationship between soluble fiber and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.81 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.81 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

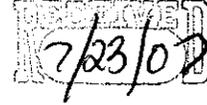
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Baltimore District Office, Office of Compliance, HFR-CE240

KONSYL PHARMACEUTICALS, INC.
8050 INDUSTRIAL PARK ROAD
EASTON, MD 21601
TELEPHONE 410-822-5192
TELEFAX 410-820-7032
www.konsyl.com

MANUFACTURING
QUALITY ASSURANCE
DISTRIBUTION
SALES & MARKETING

KONSYL®



July 17, 2007

Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Sirs:

Konsyl Pharmaceuticals, Inc. is notifying the Agency of the distribution of the following Dietary Supplements:

Bladder Control	Lactobacillus Probiotic Complex
Green Tea Diet Formula	Papaya Enzyme Digestive Aid
Green Tea Energy Formula	Fiberlin
Konsyl Balance Orange	Konsyl Balance Wild Berry

Our distribution, manufacturing and offices are located at: 8050 Industrial Park Road, Easton, MD 21601.

Enclosed are labels for the individual products.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrice B Hambleton".

Patrice B Hambleton
Manager, QA

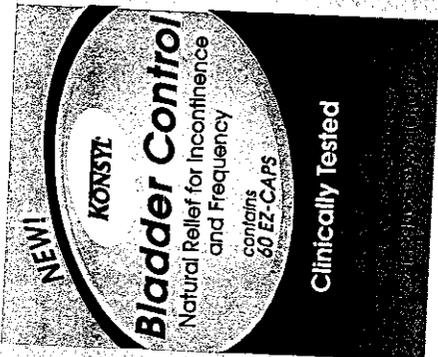
Enclosures (8)
Copies (2)

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© KONSYL Pharmaceuticals, Inc.
 Easton, MD 21601
 KONSYL Pharmaceuticals, Inc.
 Distributed By
 Email: contact@konsyl.com
 8:30 a.m. to 5 p.m. EST
 1-800-356-6795
 Questions or Comments?
 34405
 6 108584050609



*An open clinical study was conducted using pumpkin seed extract and soy isoflavone extract. The study found decreased frequency of urination during both the night and daytime, decreased frequency of incontinence, and also an improvement of sleep-related satisfaction. Individual results may vary. KONSYL does not guarantee the same results.

Dosage Recommendation: A daily dose of 2-3 capsules (600mg) of Bladder Control is recommended to provide the amount of pumpkin seed extract and soy germ isoflavones used in human studies. The studies used a higher dose for the first 2 weeks, followed by a reduced dose for the last 4 weeks. To mirror the studies, you may take 3 capsules per day for the first 2 weeks, followed by 2 capsules per day.

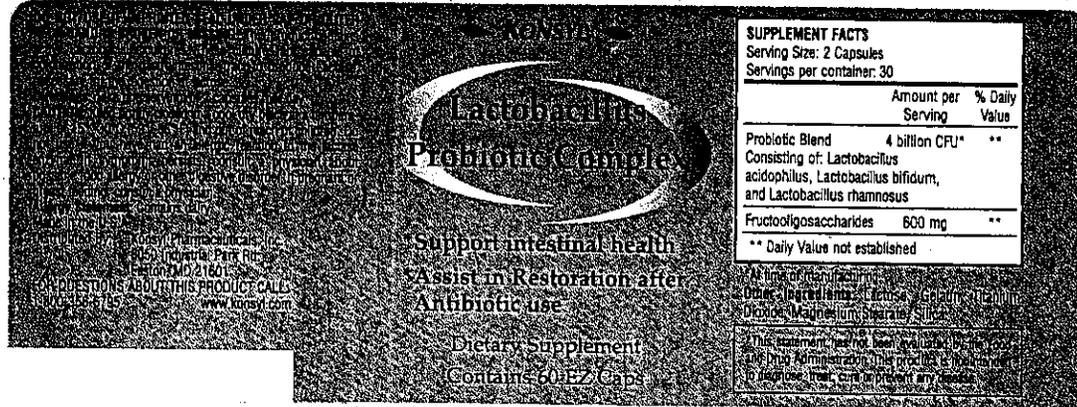
Supplement Facts		
Suggested Use: 2 - 3 capsules	Amount per Capsule	% Daily Value
Pumpkin Seed Extract (<i>Cucurbita pepo</i> L.)	525 mg	*
Isoflavone Extract from Soy Germ	75 mg	*
* Daily Value not established		
Other Ingredients: Extracts from Futarom, USA, Inc.		
CONTAINS SOY - NO ADDED: Milk, Eggs, Tree Nuts, Peanuts, Wheat, Fish, Shellfish, or ingredients from these sources.		
CAUTION: Keep tightly closed in a cool dry place, away from sunlight, between 59° - 86° F (15° - 30° C). Keep out of the reach of children. Do not use if inner seal or outer neckband is broken.		

Pumpkin seed has been used for centuries to relieve bladder problems and soy helps to balance hormones as we age. This bladder control formula has been clinically researched and shown to be effective after the first 1 to 2 weeks. Clinically shown to help: reduce incontinence*, reduce urinary urgency*, support prostate health*.

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

KONSYL PHARMACEUTICALS, INC.
 8050 INDUSTRIAL PARK ROAD
 EASTON, MARYLAND 21601

KONSYL PHARMACEUTICALS, INC.
 8050 INDUSTRIAL PARK ROAD
 EASTON, MARYLAND 21601



Product Name & Size: LB Lactobacillus Probiotic, 60's	RM #: None	Label Revision #: None	Description Type: Label
Prepared By/Date: <i>Julia L...</i> 1-25-07	Approved By/Date: MFG: <i>Rebecca...</i> 1/25/07	Approved By/Date: QA: <i>Patricia B. Hamilton</i> 1-25-07	Effective Date: 1-25-07
Form Approved By/Date: <i>Maria S. Jett</i> 10/4/03 <i>John F. Hill</i> 10-4-93			

KONSYL PHARMACEUTICALS, INC.
 8050 INDUSTRIAL PARK ROAD
 EASTON, MARYLAND 21601

NEW!

KONSYL®
BALANCE



Natural Psyllium Fiber
 & Prebiotic Inulin Fiber

NATURAL FIBER BLEND

Improves Digestive Health*
 Assists in Weight Management*
 Manages Cholesterol Levels*

50

Daily Fiber Supplement: Soluble fiber from refined psyllium husk as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of Balance supplies 1 gram of this soluble fiber.

Notice: This product should be used with at least a full glass of liquid. Using this product without enough liquid may cause choking. Do not use this product if you have difficulty in swallowing.

Directions: Stir 1 rounded teaspoon of Balance into 8 oz. of water. Stir well until thoroughly mixed. Not recommended for carbonated beverages.

- 12 years to Adult - 1 rounded teaspoon up to 3 times daily
 - 7 to 11 years - 1/2 adult dose up to 3 times daily
 - Under 6 years - Ask your doctor
- Store at controlled room temperature 20-25°C (68-77°F)

Active Ingredients: inulin (a water soluble fiber), refined psyllium husk (a natural vegetable fiber)

Inactive Ingredients: maltodextrin, citric acid, flavor, aspartame, silicon dioxide, FD&C Yellow #6, D&C Yellow #10

Supplement Facts		
Serving Size	1 rounded tsp (6g)	
Servings Per Container	50	
Amount per Serving	% Daily Value*	
Calories from fat	1	
Total Carbohydrates	5g	
Total Dietary Fiber	3.7 g	15 %
Soluble fiber	3.4 g	◆
Insoluble fiber	0.3 g	◆
Sugars	0	◆
Fat	0g	0%
Protein	0g	0%
Sodium	3mg	0%

◆ Daily Value (DV) not established
 * Percent Daily Values (DV) are based on a 2,000 calorie diet.

Warnings: Phenylketonurics: Contains phenylalanine. Do not use if printed seal is broken or missing. Keep out of reach of children. If you are pregnant or nursing a baby, ask a health professional before use.

Nutrition Information

Dietary fiber is an important part of overall good health. In addition to maintaining regularity, fiber can also help*:

- Lower cholesterol*
- Stabilize blood sugar levels*
- Control weight by helping you feel full and curb cravings*
- Maintain healthy intestinal microflora*

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

Questions or Comments?

1-800-356-6795
 8:30 a.m. to 5 p.m. EST
 E-mail: info@konsyl.com

Manufactured By:
 Konsyl Pharmaceuticals, Inc.
 Easton, MD 21601
 www.konsyl.com
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 34400 0307



Starting out with Balance?

When using this product, it is recommended to gradually increase dietary fiber. If minor gas or bloating occurs, begin with a half-dose and slowly increase the dose over several days. Always follow with 8 oz. of fluid.



KONSYL PHARMACEUTICALS, INC.
 8050 INDUSTRIAL PARK ROAD
 EASTON, MARYLAND 21601

NEW!
 Wild Berry Flavor

From **KONSYL**

CLEAR
 MIXING!

FIBERLIN

Fiber & Antioxidant



Rich Source of Fiber

Black Currant ~ Antioxidant

Improves Digestive Health*

Stimulates Probiotic Growth

NET WT 300g (10.6 OZ)
 (Fill controlled by weight, not volume)

50

TEASPOON DOSES

Directions:

Stir 1 rounded teaspoon of Fiberlin into 8 oz. of water. Stir well until dissolved. Not recommended for carbonated beverages.

- 12 years to Adult - 1 rounded teaspoon up to 3 times daily
- 7 to 11 years - 1/2 adult dose up to 3 times daily
- Under 6 years - Ask your doctor

Store at controlled room temperature 20-25°C (68-77°F)

Active Ingredients: inulin (a water soluble fiber), digestion resistant maltodextrin (a soluble fiber), black currant (an antioxidant).

Inactive Ingredients: maltodextrin, citric acid, flavor, aspartame, silicon dioxide.

Supplement Facts

Serving Size	1 rounded tsp (6g)	
Servings Per Container	50	
Amount per Serving		
		% Daily Value*
Calories from fat	1	
Total Carbohydrates	5.5g	
Total Dietary Fiber	3.6 g	15 %
Soluble fiber	3.6 g	◆
Sugars	0	◆
Fat	0g	0%
Protein	0g	0%
Sodium	3mg	0%
Black Currant Extract	72mg	◆
◆ Daily Value (DV) not established * Percent Daily Values (DV) are based on a 2,000 calorie diet.		

Warnings: Phenylketonurics: Contains phenylalanine.

Do not use if printed seal is broken or missing. Contents may settle during shipping and handling. Keep out of reach of children.

If you are pregnant or nursing a baby, ask a health professional before use.

Nutrition Information

Dietary fiber is an important part of overall good health. In addition to maintaining regularity, fiber can also help*:

- Lower cholesterol*
- Stabilize blood sugar levels*
- Control weight by helping you feel full and curb cravings*
- Maintain healthy intestinal microflora*

Healthy Antioxidants: Plant sourced antioxidants such as the black currant in Fiberlin have been found to reduce the risk for chronic diseases.*

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

Questions or Comments?

1-800-356-6795
 8:30 a.m. to 5 p.m. EST
 E-mail: info@konsyl.com

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