



0012 7 OCT -2 P12 :41

SEP - 4 2007

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

Dear Ms. Hambleton:

This is in response to your letter of August 16, 2007. Your letter responded to our July 30, 2007 letter to you concerning claims that you intended to use in the labeling of the dietary supplement product called Bladder Control.

In our July 30, 2007 letter, we stated that the claims "Natural relief for incontinence....," "Decreased frequency of incontinence....," and "[R]elieve bladder problems...[H]elp reduce incontinence, reduce urinary urgency...." suggested that the product is intended to treat, prevent, or mitigate a disease and that the product that was the subject of the claims appeared to be subject to regulation under the drug provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

In your letter of August 16, 2007, you submit a revised label for Bladder Control that bears the following claims, among others:

"Naturally Reduces Urgency and Frequency."

"Promotes Bladder Function."

"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 urinary accidents, and also an improvement of sleep-related satisfaction."

We have carefully considered the revised label claims contained in your notification and believe that the claims, in the context that they are made, continue to be disease claims rather than claims that are within the scope of claims that may be made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Act).

Frequent and urgent need to urinate are common signs or symptoms of diseases such as benign prostatic hypertrophy (BPH) and urinary tract infections. Moreover, other diseases may also cause or contribute to these symptoms (i.e., frequent or urgent need to urinate) such

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Page 2 - Ms. Patrice B. Hambleton

as inflammation of tissues near the urinary tract, bladder abnormalities such as tumors, or diabetes. Therefore, although some claims that a product is intended to promote or support bladder function may be structure/function claims within the scope of section 21 U.S.C. 343(r)(6), claims to reduce or remedy urgency and frequency of urination are not such claims because they are often associated with serious diseases or medical conditions that require diagnosis and medical intervention. Moreover, increased urgency and frequency of urination, characteristic signs and symptoms of overactive bladder, are also not in and of themselves "normal" conditions of health. Rather, they are clearly a consequence of damage to an organ, part, structure, or system of the body such that it does not function properly. Accordingly, these conditions fit squarely within the definition of the term "disease" as defined in 21 CFR 101.93(g)(1). We would also note that factors such as the severity of the condition (mild or serious) or the frequency of occurrence (occasional or frequent) would not change this conclusion.

In summary, we believe that the claims you propose to use for the product Bladder Control are disease claims that cause the product to be a drug within the meaning of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,



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

Copies:

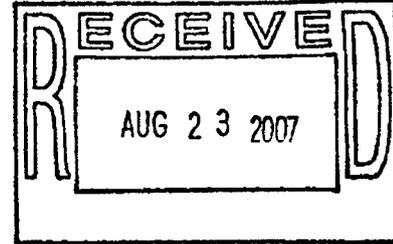
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

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

# KONSYL



August 16, 2007

Vasilios H. Frankos, Ph. D., Director  
Division of Dietary Supplement Programs  
Office of Nutrition, Labeling & Dietary Supplements  
Food and Drug Administration  
CFSAN/HFS-810  
5100 Paint Branch Parkway  
College Park, MD 20740

Dear Dr. Frankos:

Pursuant to the Agency's letter received 30 July, regarding labeling for Dietary Supplement products, enclosed please find revised labeling for review.

The product labeling enclosed is for:

|                 |                                  |
|-----------------|----------------------------------|
| Bladder Control | Konsyl Balance Orange Flavor     |
| Fiberlin        | Konsyl Balance Wild Berry Flavor |

Sincerely,

A handwritten signature in cursive script, appearing to read "Patrice B. Hambleton".

Patrice B Hambleton  
Manager, Quality Assurance

Enclosures (4)  
Copies (2)

2007-6198

1941

|   |  |                         |                              |
|---|--|-------------------------|------------------------------|
| Customer: <b>Konsyl</b>                   | Job Name: <b>34405 Bladder Control</b> | Completed by: <b>NB</b> | Checked by:                  |
| Shop Order: <b>2901</b>                   | Size: <b>2.25" x 6"</b>                | Die Tooth: <b>98</b>    | Die # <b>10-269-50</b>       |
| Material Face Stock: <b>60#Semi-Gloss</b> | Adhesive: <b>30P</b>                   | Liner: <b>40#</b>       | Off Roll Position # <b>3</b> |
| # of Colors: <b>3</b>                     | Print Colors: <b>Black</b>             | <b>1665</b>             | <b>116</b>                   |
|   |  | <b>UV Coating</b>       |                              |
|   |  |                         | Phone: 215-441-5335          |
|   |  |                         | FAX: 215-441-0997            |



**DIELINE**

Approved As Is  Approved w/Changes as noted  Submit New Proof

*Peter B. Hamilton* 8/15/07  
Signature Date

Colors shown on proof are for illustration of PMS#s indicated. Colors will be matched to the PMS#s standard on press. Please approve each item indicated or note any required changes. Return this proof sheet and an approved sample of material (if applicable) to GCI. Upon receipt of final approval we will proceed with your order.

**NEW!**

**KONSYL**

**Bladder Control**

Naturally Reduces Urgency and Frequency

contains **60 EZ-CAPS**

**Clinically Tested**

34405

0807

1-800-356-6705

8:30 a.m. to 5 p.m. EST

Email: [contact@konsyl.com](mailto:contact@konsyl.com)

Distributed By:

Konsyl Pharmaceuticals, Inc.

Exton, MD 21501

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\*In open clinical study men collected using pumpkin seed extract and soy isoflavone extract. The study found decreased frequency of urination during both the night and daytime, decreased urinary accidents, and also an improvement of sleep-related awakenings. Individual results may vary. (Study does not specify the same results.)

**Usage Recommendation:** A daily dose of 2-3 capsules (60mg) or 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 next 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  | Amount per Capsule | % Daily Value |
|---|--------------------|---------------|
| Suggested Use: 2 - 3 capsules   |                    |               |
| Pumpkin Seed Extract (Lecithin based)   | 525 mg             | -             |
| Isoflavone Extract from Soy Germ  | 75 mg              | -             |
| * Other Ingredients:  |                    |               |
| CONTAINS SOY - NO ADDED: Milk, Eggs, Tree Nuts, Peanuts, Wheat, Fish, Shellfish, or ingredients from these sources.   |                    |               |
| <b>CAUTION:</b> Keep lightly closed in a cool dry place, away from sunlight, between 59° - 85° F (15° - 30° C). Keep out of the reach of children. Do not use if liner seal or outer packaging is broken. |                    |               |

Pumpkin seed has been used for centuries to support bladder health and soy helps to balance hormones as we age. This bladder control formula has been clinically researched and shown to be effective after one week. 1 to 2 weeks. Clinically shown to help: reduce urinary frequency; 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.