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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 or 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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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

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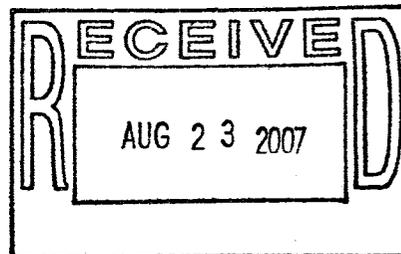
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Baltimore District Office, Office of Compliance, HFR-CE240

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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)

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