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New Dietary Ingredient Notification
For
Bacillus Polyfermenticus SCD

Submitted by

BINEX Co., Ltd.
480-2, Jangrim-Dong, Saha-Gu, Busan, Korea

May 18, 2006

Submitted To

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary
Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740-3835

From: BINEX Co., Ltd.
480-2, Jangrim-Dong, Saha-Gu, Busan, Korea

To: Division of Standards and Labeling Regulations
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Center for Food Safety and Applied Nutrition
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5100 Paint Branch Parkway
College Park, MD, 20740-3835

Re: New Dietary Ingredient Notification

Date: May 18, 2006

Dear Dr. Walker:

BINEX Co. is hereby submitting a New Dietary Ingredient (NDI) notification under 21 CFR § 190.6 for *Bacillus Polyfermenticus SCD*, the dietary ingredient in our dietary supplement, BISCAN®.

In this NDI notification for *Bacillus Polyfermenticus SCD*, we provide all of the information required under 21 CFR § 190.6. We appreciate the helpful information provided by your office to assist us in preparing this notification.

1. Name and address of distributor and/or manufacturer

Distributor and Manufacturer:

BINEX Co., Ltd.
480-2, Jangrim-Dong, Saha-Gu, Busan, Korea

2. Name of new dietary ingredient

Bacillus Polyfermenticus SCD

3. **Description of the dietary supplement that contains the new dietary ingredient**

Description of dietary ingredient

Bacillus Polyfermenticus SCD is rod-shaped bacteria in the dietary supplement that are producing 20 various enzymes. BISCAN® is a probiotic that has been used widely in Korea and Japan as a dietary supplement and pharmaceuticals to prevent and relieve the symptoms in intestinal disorder such as diarrhea and constipation. *Bacillus Polyfermenticus SCD* forms endospore. This spore coat synthesized and cortex completed *Bacillus Polyfermenticus SCD* have tolerance about outside stimulation. Therefore, *Bacillus Polyfermenticus SCD* reach intestine without significant loss.

Description of dietary supplement

BISCAN® will be sold in the U.S. as a tablet or capsule, each containing live, freeze-dried lyophilized *Bacillus Polyfermenticus SCD* strain in powdered form.

Level of new dietary ingredient in the dietary supplement

Each tablet or capsule of BISCAN® contains 83.35mg (1.667×10^7 of *Bacillus Polyfermenticus SCD* live freeze dried lyophilized strain) of *Bacillus Polyfermenticus SCD*

Recommended conditions of use

The package labeling instructs consumers to take two tablets or capsules in the morning and two in the afternoon and two in the evening for a total of 6 units/day (500mg/day)

4. **Evidence that new new dietary ingredient can reasonably be expected to be safe when used as recommended**

History of Use

Bacillus Polyfermenticus SCD originated from Japan. (Japanese biologist, Dakahasi founded *Bacillus Polyfermenticus* from air in 1933). *Bacillus Polyfermenticus SCD* has been developed by BINEX Company in Korea. For decades, *Bacillus Polyfermenticus SCD* has been manufactured and sold as dietary supplement in Korea in various forms such as tablet, capsule and granules. *Bacillus Polyfermenticus SCD* has a well-established record of safe use by people of all ages (infants, children and adults). No serious side effects have been attributed to the use of *Bacillus Polyfermenticus SCD* when used as recommended.

Scientific Publications

We have enclosed copies of four (4) scientific studies in which *Bacillus Polyfermenticus SCD* was tested as a therapeutic agent to treat or prevent various forms of diarrhea and constipations and one (1) presentation slides that show various comparison charts between *Bacillus Polyfermenticus SCD* and Kimchi's *Lactobacillus*. Complete and accurate English translations of articles that were originally published in Korean have been provided. The complete citations of these four scientific publications are provided in the bibliography attached as Appendix I. In addition, we are providing the actual local sale of commercially available products that contain *Bacillus Polyfermenticus SCD* manufactured by BINEX in Appendix II.

Summary

Lactobacillus, a bacillus that is very similar to *Bacillus Polyfermenticus SCD*, is found in Korean native fermented vegetable dish known as Kimchi. Kimchi, one of Korean traditional fermented food, in addition to Korean hot pepper paste (gochujang), soybean paste (doenjang) and soy sauce, is a Korea-representing food, true to the name, and significant subsidiary food not to be ruled out of Korean food culture. Until recently, very little studies were performed on Kimchi and its nutritional and functional value. However, the domestic researchers have reported on the findings from reviewing Kimchi's value as a health food, step by step. With these studies, BINEX researchers presumed the reason why incidence of large intestine cancer is lower to Korean is that they take so much Kimchi and they believe that fermented Kichi liquid has its direct anti-cancer effect against MG-63 human body osteosarcoma cell and K-562 leukaemia cell and also observed, from their anti-mutation experiment, that methanal extract of the fermented Kimchi has mutation-checking effect against carcinogenic substances aflatoxin B1 and N-methy-N-nitgro-N-nitrosoguanidine(MNNG). They believe that microorganism involving in fermentation of Kimchi has its cancer-restraining effect and from their experiment with rat administered Kimchi fermented bacillus in vivo, believe that Kimchi fermented bacillus give its counteracting poison effect against the poisonous substance(a-naphthol) and cell wall extract of *Lactobacillus plantarum* of the fermented bacillus involved in fermenting Kimchi has direct anti-cancer effect against ascites cancer and solid cancer triggered by sarcoma 180 cell lines.

Study showed Kimchi, a Korean traditional fermented food that is known to have nutritional and functional value as a health food, had the characteristics of cancer-preventing effect by way of researching antigenotoxic effect of dominant fermented bacillus involved in fermenting Kimchi by the swaid SCGE(Single Cell Gel Electrophoresis) or comer assay.

Therefore, both an extensive history of traditional food consumption of Kimchi which contains *Lactobacillus* and commercial use of BISCAN® in Korea have shown that *Bacillus Polyfermenticus SCD* is safe when used at the recommended dose in BISCAN® (500mg/day).

Please do not hesitate to contact me if you have any questions about the information provided in this NDI notification or if you need any additional information.

Best regards,



John H Choi
Authorized Representative and US Agent for BINEX Co.
Piscium International, Inc
jchoi@pisciuminternational.com

Appendix I
Bacillus Polyfermenticus SCD Bibliography

Scientific Publications

1. Choi, JW., Park JH., Ji, ST., Choi, OB., Shin, HK. Antigenotoxic effect of dominant bacterial isolates from Kimchi *in vitro*. Korean J. Food. Sci. Technol. 31: 1071-1076 (1999)
2. Jeon, Kyung Dong 1998. Microbiological identification, antimicrobial activity and enhanced production of Bisroot strain. *MS Thesis, Kyungnam University*
3. Lee, K-H., Jun, K-D., Kim, W.S. and Paik, H.D.: Partial characterization of polyfermenticin SCD, a newly identified bacteriocin of *Bacillus Polyfermenticus*. *Letter in Applied Microbiology* 32, 146-151 (2001)
4. Paik, H-D., Jung, M-Y., Jung, H.Y., Kim, W.S. and Kim, K-T. Characterization of *Bacillus Polyfermenticus SCD* for oral bacteriotherapy of gastrointestinal disorders. Korean J. Food Sci. Technol. 34: 73-78 (2001)

Appendix II

1. Amount of Actual Local Production sale of products that contain *Bacillus Polyfermenticus SCD* manufactured by BINEX (2000-2004)