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VIA FEDERAL EXPRESS

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OFFICE OF SPECIAL NUTRITIONAL PRODUCTS
LABELING AND DIETARY SUPPLEMENTS
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration (HFS 800)
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Notification for Certain Types of Statements on Dietary Supplements

Dear Sir or Madam:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, LLC, 75 West Center Street, Provo, Utah 84601, intends to market a dietary supplement product with the following label and marketing statements on nutritional support:

Product: PRO BIO PCC
Statements: Maintains a healthy gastrointestinal environment

Proven to resist stomach pH and bile acids in order to effectively colonize the gut, ProBio PCC is manufactured to ensure more active organisms are delivered to the lower digestive system for maximum benefit.

As a dietary supplement, ProBio PCC increases healthy bacterial levels, supports the growth of beneficial flora in the digestive tract and helps maintain desirable gastrointestinal comfort.

As a dietary supplement, take one capsule daily with food to promote normal gastrointestinal health.

Reduces symptoms associated with occasional GI discomfort.

Promotes digestive comfort and normal regularity.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, LLC, has substantiation that these statements are truthful and not misleading.

Sincerely,

Carsten Smidt, Ph.D., FACN
Sr. Director of New Product Research and
Development

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