



March 16, 2004

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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:

Products:

IgG Boost™

Statements:

- Boost your immunity
- Immunoglobulins, a key immune component in colostrum, boosts the immune system for protection in a world full of harmful microorganisms
- The immunoglobulins (IgG) in bovine colostrum are now shown to provide immune benefits to people of all ages

We 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,

Mark Bartlett, Ph.D.
Senior Scientist
Pharmanex® Research and Development

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