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July 12, 1999

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7/19/99

Office of special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Vistrum™

Ladies and Gentlemen:

Pursuant to Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act, and FDA regulation 21 CFR 101.93, you hereby notified that VISTRUM Dietary Supplement was first marketed in the United States on July 26, 1999 with the following statement of nutritional support included in the product's labeling:

1. Vistrum™ Immune and Nutritional Supplement
2. Supports gastrointestinal health

The finished product, including a proprietary blend of Proventra™ brand natural immune components from dairy cow colostrum, probiotics and a prebiotic, purchased from GalaGen, Inc. The finished product is manufactured by American Institutional Products, Inc., P.O.Box 800, Austin, MN 55912. Proventra is a source of supplemental natural immune factors and is one subject of the above-identified statements of nutritional support. Vistrum also provides supplemental beneficial live active cultures (probiotics) and inulin (prebiotic) to support gastrointestinal health.

It is hereby certified that the information in this notice is complete and accurate, and that our company has substantiation that the above-identified statements of nutritional support are truthful and not misleading.

Very truly your,

Laura L. Simes

Laura L. Simes
American Institutional Products, Inc.



1275 Red Fox Road, MS 7420
Arden Hills, Minnesota 55112-6943

Mailing Address: P.O. Box 64314
St. Paul, Minnesota 55164-0314

July 8, 1999

Laura Simes
American Institutional Products
P.O. Box 800
Austin, MN 55912

Re: Proventra™ Brand Natural Immune Components in a
proprietary blend with active cultures and inulin.

Dear Laura:

GalaGen Inc. is the manufacturer of Proventra™ brand natural immune components from dairy cow colostrum. For the product "Vistrum™", this ingredient has been combined with *Lactobacillus acidophilus* NCFM, *Bifidobacterium longum* and *Bifidobacterium infantis*, probiotic active culture strains sourced from Rhodia Inc., and inulin, a source of fructose oligosaccharides, sourced from Orafit Inc. This proprietary blend of three active ingredients is designed to provide a dietary source of supplemental natural immune components and support gastrointestinal health.

This information has been designated on the label for "Vistrum™" by the phrases "immune and nutritional supplement" and "supports gastrointestinal health."

Our company maintains a file of literature references and internal research to substantiate that the above-identified statements of nutritional support are truthful and not misleading.

Very truly yours,

GalaGen Inc.

By *John J. Bostwick*

Title *V.P. Research + Development*