

Procter & Gamble

The Procter & Gamble Company
Health Care Research Center
8700 Mason-Montgomery Road, Mason, Ohio, 45040

NOV 22 P2:25

October 27, 2005

Via Overnight Mail

OCT 31 2005

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Sir or Madam:

This letter serves as a Notification pursuant to 21 CFR § 101.93 and Section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) that The Procter & Gamble Company is using the following statements on the label or in the labeling of Align™, a daily dietary supplement containing the dietary ingredient *Bifidobacterium infantis* 35624.

Structure/Function claims for gastrointestinal health:

- Works with your digestive system.
- Maintain your digestive balance.
- Helps you stay on track for normal digestive health.
- Use on a daily basis to help your GI system reach its balanced state.
- Clinically proven to promote and maintain natural, healthy digestive balance.
- Clinically proven to support and maintain normal healthy bowel function.
- Experience the benefits of having a balanced, strong and healthy digestive system.
- Helps deal with an imbalance of intestinal bacteria that can cause occasional digestive problems
- Promotes normal, healthy bowel function.
- A natural defence against an array of occasional digestive upsets, such as diarrhea, constipation, urgency, gas, and bloating.
- Promotes natural, balanced digestive health.
- Promotes the natural balance of your digestive system.
- Helps restore the balance of intestinal bacteria.
- Keeps your system balanced and maintains your overall digestive health.
- Helps maintain a healthy, balanced digestive system.
- A natural supplement that promotes digestive health.

97S 0162

LET 16 986

- Clinically proven to improve digestive balance.
- Delivers “good” bacteria to your digestive system.
- Delivers millions of “friendly” bacteria to work within your digestive system.
- Taken every day, helps maintain “friendly” bacteria at desirable levels, where they can work as a buffer against common triggers of occasional digestive upsets.

These statements are accompanied by the DSHEA disclaimer as required by 21 CFR § 101.93. Consistent with 21 CFR § 101.93, P&G has substantiation that these statements are truthful and not misleading. The product is distributed by Procter & Gamble, Cincinnati, OH, 45202.

If you have any questions or comments relating to this notification, please do not hesitate to call me at 513-622-1599, or e-mail johnson.bn@pg.com. As required by 21 CFR 101.93, this original notification is submitted along with two copies.

Sincere Regards,
THE PROCTER & GAMBLE COMPANY



Bradley N. Johnson, Ph.D.,
Personal Health Care, Regulatory Affairs