

**PURDUE**

**Purdue Products L.P.**

One Stamford Forum  
Stamford, CT 06901-3431  
www.purduepharma.com

April 5, 2004

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

APR 13 2004

Dear Sir or Madam:

Purdue Products L.P. submits the information in this notification pursuant to 21 C.F.R. Subpart F, section 101.93 as notice of marketing structure/function claims for Senokot® brand Wheat Bran Fiber Supplement.

**Supplement:** Senokot® brand Wheat Bran Fiber Supplement

**Manufacturer/  
Packager:** IFP Custom Processing Group  
2125 Airport Drive  
Faribault, MN 55021

**Distributor:** Purdue Products L.P.  
One Stamford Forum  
Stamford, CT 06901-3431

**Statement Text:**

- "Helps maintain regularity"
- "Helps maintain normal bowel function"
- "Gives you the regularity benefits you want from a fiber supplement"
- "For relief of occasional constipation, such as caused by changes in dietary habits or travel. This product is not intended for use with chronic constipation or constipation associated with a pre-existing medical condition"

**Name of dietary ingredient that is the subject of statement:** Wheat Bran

**Name of dietary supplement:** Senokot® brand Wheat Bran Fiber Supplement

All of the above statements will be followed by an asterisk that links it to the following boxed warning, "This statement has not been evaluated by the Food and Drug Administration. The product is not intended to diagnose, treat, cure or prevent any disease."

I hereby certify that the information presented and contained in this notice to be accurate and in compliance with supplement label regulations, and that Purdue Products L.P. has substantiation to verify that the statements are truthful and not misleading.

  
Anthony Santopolo, M.D.

Vice President, Regulatory Affairs  
Purdue Products L.P.

4/5/04  
Date

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*Dedicated to Physician and Patient*