

Letter

ARTJEN COMPLEXUS HOLDINGS CORP.

December 1, 2004

Office of Nutritional Products  
Labeling and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

DEC 02 2004  
O-B/FDA

Dear Sir or Madam:

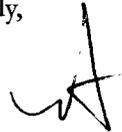
Please find attached a *New Dietary Ingredient Notification* for  $\alpha$ -cyclodextrin to be marketed under the trade name FBCx™. The attachments include:

- ❖ The notification
- ❖ Appendix A
  - Wacker Chemical Corp. Specification Sheet
  - Wacker Chemical Corp. Confirmation of GMP
  - Wacker Chemical Corp.  $\alpha$ -Cyclodextrin Test Methods
- ❖ Appendix B
  - Tablet Formulation from Jamieson/Nutricorp
  - Jamieson/Nutricorp Health Canada Establishment License
  - Chewable Tablet Formulation
  - Archon Vitamin Corporation State of New Jersey GMP Certificate
- ❖ Appendix C
  - Copies of two FAO/WHO documents pertaining to safety
  - Correspondence confirming GRAS status of  $\alpha$ -cyclodextrin
  - Copies of Referenced Articles

Please be advised that this product is in compliance with the labeling requirements as set forth in the federal registry.

We look forward to a positive response from your office.

Sincerely,



Joseph D. Artiss, Ph.D., FACB  
Vice President