ARTJEN COMPLEXUS INC.

August 27, 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

RECEIVED
SEP 08 2004
BY: LB/FDA

Dear Sir or Madam:

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

- The notification
- Copies of two FAO/WHO documents pertaining to safety
- A copy of a correspondence confirming GRAS status of α-cyclodextrin
- Copies of eight (8) document pertaining to animal and human tissue culture studies

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

510 WESTCOURT PLACE • 251 GOYEAU STREET • WINDSOR • ON • N9E 2T2
PHONE: 519-919-0814 • FAX: 519-966-8901

89491

NEW DIETARY INGREDIENT NOTIFICATION – PREMARKET NOTIFICATION

August 27, 2004

1. **MANUFACTURER/DISTRIBUTOR-**

   ArtJen Complexus Inc.
   510 Westcourt Place
   251 Goyeau Street
   Windsor, Ontario N9E 2T2
   Canada

2. **NAME OF NEW DIETARY INGREDIENT-**

   α-Cyclodextrin – Chemical Abstract Number [10016-20-3]
   Trade name – FBCx™

3. **Description of the Supplement-**

   The supplement will be in the form of tablets and/or chewable tablets.

   i. Each tablet will contain 1.0g of α-cyclodextrin. Chewable tablets may contain either 1.0 or 2.0g of α-cyclodextrin.

   ii. It is recommended that two 1g tablets or chewable tablets or one 2g chewable tablet be consumed within one hour, before, after or during the consumption of a fat containing meal.

4. **Evidence of Safety-**

   Please find a listing of evidence below; copies of these documents have been attached:

   i. Joint FAO/WHO Expert Committee on Food Additives, Fifty-seventh meeting, Rome, 5-14 June 2001. Establishes that the *Acceptable Daily Intake* of α-cyclodextrin is *Not Specified.*

   ii. Joint FAO/WHO Expert Committee on Food Additives, Sixty-third meeting, Geneva, 8-17 June 2004. Confirms that the *Acceptable Daily Intake* of α-cyclodextrin is *Not Specified.*

   iii. Correspondence by McColl, Diane B. of Hyman, Phelps & McNamara, P.C., to Gimber, Christian of Wacker Chemical Co.- This document confirms that an independent panel of qualified scientific experts concluded, based upon scientific procedures, that α-cyclodextrin is GRAS (Generally Regarded As Safe).

   iv. A listing or scientific, peer-reviewed studies conducted in various animal species and human tissue culture follow:

Agu, R., M. Jorissen, et al. (2000). "Safety assessmewnt of selected cyclodextrins - effect on ciliary activity using human cell suspension culture model exhibiting vitro ciliogenesis." Int J Pharmaceu **193**: 219-226.

Bar, A. (2004). "Preface." Reg Toxicol Pharmacol **39**: S1-S2.

Bar, A., C. Krul, et al. (2004). "Safety evaulation of an alpha-cyclodextrin glycosyltransferase preparation." Regul Toxicol Pharmacol **39**: S47-S56.

Lina, B. and A. Bar (2004). "Subchronic (13-week) oral toxicity studies of a-cyclodextrin in dogs." Regul Toxicol Pharmacol **39**: S27-S33.

Lina, B. and A. Bar (2004). "Subchronic oral toxicity studies with a-cyclodextrin in rats." Regul Toxicol Pharmacol **39**: S14-S26.

Van Ommen, B., A. DeBie, et al. (2004). "Disposition of ^{14}C-cyclodextrin in germ-free and conventional rats." Regul Toxicol Pharmacol **39**: S57-S66.

Waalkens-Berendsen, D. and A. Bar (2004). "Embryotoxicity and teratogenicity study with a-cyclodextrin in rats." Regul Toxicol Pharmacol **39**: S34-S39.

Waalkens-Berendsen, D., A. Smits-van Prooije, et al. (2004). "Embryotoxicity and teratogenicity study with a-cyclodextrin in rabbits." Regul Toxicol Pharmacol **39**:S40-S46.

5. Signed:

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