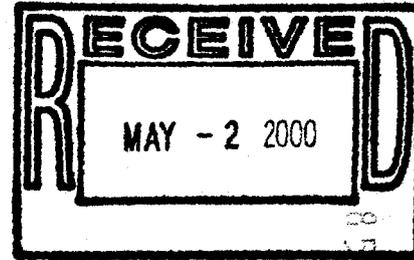




Functional Product

April 26, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington D.C. 20204



Dear Sir or Madam:

This letter will serve as a 30-day notification pursuant to Section 6 of the Dietary Supplement Health Education Act (DSHEA); Rule 21 C.F.R., Section 101.93; and the Federal Food, Drug & Cosmetic Act, Section 403 (r)(6).

Developer and Distributor of the products containing the structure-function claims set forth herein: Functional Products L.L.C.; 1179 Atlantic Blvd., Atlantic Beach, FL 32233; Tel: (904) 249-8074; Fax: (904) 249-8467.

Functional Products L.L.C. develops and markets for sale in the United States the following products which bear structure-function claims on their packaging:

- A. Brio Effervescent Wafers; Vitamin C & Echinacea
Contains: Echinacea and Vitamin C.
Text of Statement: Immune System Enhancement
- B. Vivex Heart Adjuvant
Contains: standardized Hawthorn Extract
Text of Statements: "To maintain a strong, stable, and regular heartbeat." "Our Heart Adjuvant helps maintain a strong, stable, regular heartbeat."
- C. Vivex Vein & Artery Adjuvant
Contains: Vitamin E, Garlic Powder
Text of Statements: "To maintain proper artery tension, and a clean, healthy structure of the circulatory system. Supports cardiovascular health." "Our Vein & Artery Adjuvant supports cardiovascular health by maintaining proper tension in the arteries and veins."
- D. Vivex Feverfew Adjuvant
Contains: standardized Feverfew Extract
Text of Statements: "To relieve occasional headache pain and pressure. To maintain healthy blood vessel tone." "Our Feverfew Adjuvant relieves occasional headache pain and pressure."

97S - 0162

Also see docket 97S-0162

LET 5361