DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3032 Bryan Street
Dallas, Texas 75204-6191

REGULATORY LETTER

February 18, 1988

Ref: 88-DAL-13

Certified Mail
Return Receipt Requested

Mr. Albert J. Ball, M.H., D.N.
R.J. Systems
6001 Marble Avenue, N.E.
Suite 14
Albuquerque, N.M. 87110

Dear Mr. Ball:

During an investigation of your repacking operation by an investigator from this office on January 15 & 19, 1988, a serious violation of the Federal Food, Drug and Cosmetic Act with respect to Unsaturated Fatty Acid Capsules containing Oil of Evening Primrose and labeled as a dietary supplement was revealed as follows:

SECTION	BRIEF DESCRIPTION
402(a)(2)(C)	Unsaturated Fatty Acid capsules are adulterated in that they contain, a food additive, Oil of Evening Primrose, (Gamma Linolenic Acid) which is unsafe within the meaning of Section 409, because there is no regulation in effect which provides for its safe use and there is no exemption in effect for such use pursuant to Section 409.

We request that you take prompt action to correct this violation. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions as provided by law. These include, seizure and/or injunction.

We also noticed that the labeling (promotional material) accompanying many of your products make drug type claims. Those statements make the articles new drugs without approved new drug applications as required by Section 505(a) of the Federal Food, Drug, and Cosmetic Act.

We request that you advise us in writing within ten (10) days of receipt of this letter as to the specific actions taken or intended to be taken to correct the current violations and prevent future violations. Please direct your response to Mrs. Maritza Colon-Pullano, Compliance Officer, Food and Drug Administration, 3032 Bryan St., Dallas, Texas 75204.

Sincerely,

Gerald E. Vince

Gerald E. Vince
District Director