

September 15, 1988

REGULATORY LETTER

Certified Mail - Return Receipt Requested

Harvey Mizes, President  
Bajamar Women's Healthcare  
9606 Dielman Rock Island  
P.O. Box 12411  
St. Louis, MO 63132

88-STL-018

Dear Mr. Mizes:

We recently reviewed the labeling for your food (dietary supplement) product "BAJAMAR'S ESSENTIAL FATTY ACIDS" capsules and found it to be in serious violation of the Federal Food, Drug, and Cosmetic Act.

Section

Brief Description

402(a)(2)(C)

The article of food is adulterated in that it bears or contains a food additive, gamma linolenic acid, which is unsafe within the meaning of Section 409 because there is no regulation in effect pursuant to Section 409 prescribing the conditions under which the additive may be safely used, and no exemption is in effect for its use or intended use.

We request that you reply within 10 days of your receipt of this letter stating the actions you have taken or will take to correct this violation. If such action is not taken promptly, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 CFR 332 and 334).

Your product "Evening Primrose Oil", which also contained gamma linolenic acid, was seized in November 1987 [Eastern District of Missouri 87-2063C(4)]. Products that contain linolenic acid, including those with oil of evening primrose, black currant seed oil, or any other similarly identified product are also deemed to be adulterated foods.

Your response should be directed to Spencer L. Sorenson, Compliance Officer, at the address referenced in the letterhead.

Sincerely,

Raymond K. Hedblad  
Director  
St. Louis Branch