IMPORT ALERT

ADFS-DFRG (HFO-415)
Field Compliance Branch

OIL OF EVENING PRIMROSE

No.: 66-04 - Revised
Date: June 11, 1985

BACKGROUND

Oil of Evening Primrose (gamma linolenic acid) is currently being promoted by some firms as a panacea for a wide range of conditions such as PMS, eczema, benign breast disease, obesity, alcoholism (cures damage done to brain by excessive drinking) and hyperactive children. The Agency is unaware of any evidence to establish the safety and effectiveness for such claims.

FDA was recently informed by one firm, Efamol Research Inc., Kentville, Nova Scotia, that they are conducting clinical trials with Oil of Evening Primrose and have approximately 30 U.S. physicians working with them. To our knowledge, Efamol Research Inc. has not submitted IND's for Oil of Evening Primrose. We are unaware of any domestic manufacturing of Oil of Evening Primrose and the article is being imported from Canada and England with either food or drug labeling.

1. Detain Oil of Evening Primrose offered for entry:
   a. If labeled for drug use and there is labeling with drug claims, charge:

      "The article is violative within the meaning of 801(a)(3) in that it appears to be a new drug without an approved New Drug Application (NDA) pursuant to section 505(a)."

   b. If labeled as a food, charge:

      "The article is violative within the meaning of 801(a)(3) in that it appears to contain Oil of Evening Primrose (Gamma Linolenic Acid) an unsafe food additive within the meaning of section 409."

   c. If entered unlabeled but in capsule form, detain based on intended use using both food and drug charges in a and b above.

2. If Oil of Evening Primrose enters as unlabeled, bulk, liquid, release with comment as follows:

   "Oil of Evening Primrose cannot legally be sold as a food or a drug except under the following conditions: 1) If sold as a drug, it is considered a new drug and the responsible person must hold an approved New Drug Application (NDA); 2) If sold as a food, it is considered a food additive, and prior to marketing a food additive petition must be submitted to FDA in accordance with Parts 170.35 and 171.1 of Title 21 of the code of Federal Regulations and be approved by FDA."