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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
830 THIRD AVENUE
BROOKLYN, NEW YORK 11232 1593

CABLE ADDRESS: NYFOODRUG

2 FEB 1988

REGULATORY LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Irving Willner, President
Willner Chemists, Inc.
330 Lexington Avenue
New York, NY 10016

Ref: 21-NYK-88

Dear Mr. Willner:

During an inspection of your firm on December 8 and 15, 1987, our investigator documented that you are engaged in the distribution of various oil of evening primrose products labeled for use as dietary supplements. Our review of the labels has revealed that these products are in serious violation of the Federal Food, Drug, and Cosmetic Act as follows:

<u>Section</u>	<u>Brief Description</u>
402(a)(2)(C)	Oil of evening primrose, labeled for food use, is adulterated in that it is a food additive which is unsafe within the meaning of Section 409 because there is no regulation in effect which was issued under that section prescribing the conditions under which such additive may be safely used, and there is no exemption in effect for its use or intended use.

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 provided under the law. These include seizure and/or injunction.

Please notify us in writing within ten days of your receipt of this letter of the specific actions you have taken to correct the violation. Your response should be sent to Clarence L. Waltrous, Director, Compliance Branch at the above address.

Sincerely,

Joseph J. Faline
Joseph J. Faline
District Director