DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

REGULATORY LETTER

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2
Telephone (213) 252-7583

November 15, 1988

Mr. Blake Sawyer, Owner
Le Tan
2675 West Highway 89-A, Suite 455
Sedona, AZ 86336

LA-09-9

Dear Mr. Sawyer:

A Food and Drug Administration review of a sample collected of your product,"Le Tan CANTHAXANTHIN *** 80 tablets *** each tablet contains 30 mg of canthaxanthin ..." and accompanying promotional literature (labeling) entitled "Canthaxanthin Information", leads us to conclude that your product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

SECTION	BRIEF DESCRIPTION
601(e)	The article, Le Tan CANTHAXANTHIN Tablets is adulterated in that it is a cosmetic within the meaning of Section 201(i) of the Act, since its represented and suggested use is to color the human body, and it is not hair dye and it is, or contains, a color additive, namely canthaxanthin, which is unsafe within the meaning of Section 706(a) because there is no regulation in effect under Section 706(b) for such use or intended use of canthaxanthin.
601(a)	The article is misbranded because its labeling is false and misleading. The entire paragraph 7D of the brochure which is supplied to the customers when they purchase the Canthaxanthin Tablets, is false or misleading because it represents, suggests, or implies that the product may be legally sold as a cosmetic, that the FDA has closed down several firms and that FDA has approved this particular product.

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 such as seizure and/or injunction.

Please advise us within ten (10) days of receipt of this letter as to the specific actions taken or intended to be taken, including measures to prevent the recurrence of the violation, and an explanation of any forseen delays in correcting the violation.

Your response should be directed to:

Mr. Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
1521 West Pico Boulevard
Los Angeles, CA 90015

Sincerely,

George J. Gerstenberg
District Director

[redacted]

/sk