



April 9, 1997

WARNING LETTER

SJN-927+11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Rubén De Quesada
President
Omega, Inc.
P.O. Box 1831
Carolina, Puerto Rico 00984

Dear Mr. De Quesada:

During an inspection of your drug manufacturing facility located at Julio N. Matos Industrial Park, Building F, #10, Carolina, Puerto Rico conducted from March 4 to March 6, 1997, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's manufacture of topical liquid drug products causing these drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to test finished drug products for conformance to appropriate final specifications prior to release in accordance with 21 CFR 211.165(a) in that:

You have failed to test any lots of finished product Isopropyl Rubbing Alcohol 70% for potency and acidity in accordance with the U.S.P. monograph for Isopropyl Rubbing Alcohol.

You have failed to test any lots of finished product Hydrogen Peroxide 3% Topical Solution U.S.P. for identification, assay, heavy metals, barium, acidity, nonvolatile residue or limit of preservative in accordance with the U.S.P. monograph for Hydrogen Peroxide Topical Solution.

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2. Failure to include the lot or control number of drug products in distribution records in accordance with 21 CFR 211.196.

3. Failure to maintain written records of calibration of mechanical equipment used in the manufacture of drug products in accordance with 21 CFR 211.68(a) in that:

There were no records to indicate that the flow meters used to measure amounts of water and active ingredients for the preparation of Isopropyl Rubbing Alcohol 70% and Hydrogen Peroxide 3% Topical Solution had been calibrated.

We acknowledge receipt of your letter, dated March 18, 1997. Your responses to the FD-483 observations appear, if fully implemented, to adequately address the concerns of the investigators. However, your letter dated July 13, 1994 following an inspection of the same facility on June 13 & 14, 1994 makes commitment to correct the same deficiencies as listed in # 1, 2, & 3 above and the current inspection has found that the problems were not corrected.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify the San Juan District office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

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Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

Jeremiah D. Beckwith, DIB
for
Samuel Jones
District Director

cc: Carlos E. Román, Q.C. Manager