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DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, COMPLIANCE TEAM
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122
(504) 589-7166 Fax 589-4657

April 8, 1997

WARNING LETTER NO. 97-NOL-37

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Donald R. Owen, President
Biosyn, Inc.
5701 Crawford Street, Suite I
Harahan, LA 70123

Dear Dr. Owen:

During an inspection of your facility, on March 4, 6-7, 10, 13, and 19, 1997, our investigator documented deviations from the Current Good Manufacturing Practice regulations (Title 21, *Code of Federal Regulations*, Part 211) regarding your firm's pharmaceutical manufacturing operation. These deviations cause your OTC sunscreen drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection revealed that there is no assurance that your OTC sunscreen drug products meet applicable standards of identity, strength, quality, and purity in that you have failed to comply with certain Current Good Manufacturing Practices including: no expiration date on finished drug products and failure to conduct stability studies; failure to validate the test methods used to identify active ingredients; failure to include strength of the active ingredients in product specifications; no written procedures for the responsibilities and procedures of the Quality Control Unit, for the warehousing and distribution of finished product, or for several other drug processing operations; no written procedures and records of the cleaning and calibration of certain equipment; no documentation of microbiological tests performed and test results of the deionized water system; failure to maintain an approved label as part of the master production and control records; and, several other record keeping deficiencies.

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.

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

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to David J. LeRay, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. LeRay.

Sincerely,

for
James E. Gamet

James E. Gamet
District Director
New Orleans District Office

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Enclosure: 21 CFR, Part 211