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June 14, 2001

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Ref. KAN 2001-026

Salvatore Rudy Cosentino, Chairman of the Board  
Marianna, Inc.  
11222 I Street  
Omaha, NE 68137-1296

Dear Mr. Cosentino:

During an inspection of your firm conducted on April 24 - May 3, 2001 it was discovered you are manufacturing human and veterinary pharmaceuticals and cosmetics, as defined by Section 201(g)(1) and Section 201(i), respectively, of the Federal Food, Drug, and Cosmetic Act (the Act). Our investigator documented serious deviations from Title 21 Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211), the current Good Manufacturing Practice (cGMP) regulations for the manufacture of pharmaceuticals. These deviations cause your pharmaceutical products to be adulterated under Section 501(a)(2)(B) of the Act.

Deviations noted include, but are not limited to, the following:

- Failure to have a Quality Control Unit that reviews and approves batch product records, written manufacturing procedures, product specifications, batch releases, consumer complaint investigations/responses and raw material acceptance.
- Failure to determine if a batch contains the acceptable level of active ingredient prior to distribution into interstate commerce.
- Failure to have master production records documenting critical manufacturing steps.
- Failure to perform adequate stability testing on released product.
- Failure to have adequately documented and verified the performance of your equipment cleaning procedures.
- Failure to demonstrate manufacturing procedures are adequate to assure your pharmaceutical products are processed in a manner to assure efficacy and safety.

In addition our records indicate your firm is not registered with the Food and Drug Administration as a drug manufacturer and your products are not listed. This causes the

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pharmaceutical products you distribute to be misbranded within the meaning of Section 502(o) of the Act.

At the close of the inspection these and other deficiencies were discussed with William Cosentino, Vice-President and/or were documented on a Form FDA483. A copy of this document is enclosed for your information.

The above listed deviations are not intended to be an all-inclusive list of the deficiencies that may exist at your firm. It is your responsibility to assure that your products meet the requirements of the Act and that you properly adhere with the implementing regulations (cGMPs). Federal agencies are advised on the issuance of all Warning Letters about drugs so that they may consider the information when determining the awarding of contracts. In addition Warning Letters are considered when export certificates are requested.

Your should take prompt action to correct these violations. Failure to correct the deficiencies that exist at your firm may result in further regulatory action without further notice including seizure and/or injunction.

Please notify this office within fifteen (15) working days after receipt of this letter. Your response should specifically identify the actions you will take to correct the violations and to prevent a reoccurrence of the violations. Your response should indicate when each of the corrections noted during the inspection and in this correspondence will be completed.

Your reply should be directed to Ralph J. Gray, Compliance Officer at the above address.

Sincerely,

  
Charles W. Sedgwick *for*  
District Director  
Kansas City District Office

Enclosure

Cc: William Cosentino, Vice-President  
Marianna, Inc.  
11222 I Street  
Omaha, NE 68137-1296