



# U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT  
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

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Telephone: [718] 965-5300 [Ext 5053]

## **WARNING LETTER**

November 4, 1996

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Robert Corinaldesi, President  
R.J.S. Scientific, Inc.  
40 Harbor Park Drive  
Port Washington, New York 11050

Ref: 10-NYK-97

Dear Mr. Corinaldesi:

An inspection of your drug manufacturing facility, located at 40 Harbor Park Drive, Port Washington, New York 11050 was conducted between September 6 and 12, 1996. This inspection documented that your facility contract manufacturers the products Leg Magic Concealing Makeup Sun Protection Formula (Beige #2, Golden Brown #2, Very Light #0, Medium Brown #7 and Light Brown #6) for Roberts Proprietaries, located at One Anderson Avenue, Moonachie, NJ 07074 under the Lydia O'Leary/Covermark label. These products are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigator also documented deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals [Title 21, Code of Federal Regulations (CFR), Part 211]. These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act as follows:

- 1) Failure to validate the Deionized Water System.
- 2) There were no in-process and finished product specifications and acceptance criteria to assure batch uniformity of the Leg Magic Concealing Makeup.

- 3) The batch production and control records failed to include the procedural steps in the manufacturing, packing, holding and testing for each batch of drug product produced. Specifically they failed to: a) describe and identify the mixing and filling equipment used; b) specify manufacturing and filling instructions; c) record results of in process inspection and testing; d) and include a statement of the actual and percentage theoretical yield of finished products and the actual yield of the bulk.
- 4) Laboratory records fail to include stability testing data to assure that the drug products meet standards of identity, strength, quality and purity throughout the expiry period.
- 5) There was no testing of raw material components as required by your Standard Operating Procedure for "Sampling Procedure Raw Materials and Validation of Vendor (Manufacturer) Certificate of Analysis and/or Testing."
- 6) There were no records kept of the maintenance, cleaning, sanitizing and inspection of equipment used in the manufacture of finished products.
- 7) During the manufacturing of your products, employees were observed not wearing the appropriate head covering as required by your written Standard Operating Procedure for "General Cleaning and Sanitation Guidelines for the Manufacturing, Processing, Packaging, Holding Equipment and Facilities of RJS Scientific."

The above list of violations is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all of your firm's products are in compliance with all requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices 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. These include a seizure and/or injunction.

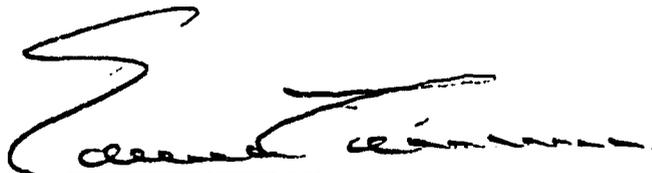
You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

R.J.S. Scientific, Inc.

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Your reply should be sent to Domestic Compliance Branch, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, Attention: Anita Fenty, Compliance Officer.

Very truly yours,



Edward T. Warner  
District Director  
New York District Office  
Food and Drug Administration

ETW/af

cc: Keith Roberts, President  
Roberts Proprietaries  
One Anderson Avenue  
Moonachie, NJ 07074