



DEPARTMENT OF HEALTH & HUMAN SERVICES

M924N

HFL-35
Public Health Service

May 20, 1997

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

WARNING LETTER
SJN-97-15

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. José Rivera
President
Specialties Chemical, Inc.
P.O. Box 277, Playa Ponce
Ponce, Puerto Rico 00634

Dear Mr. Rivera:

During an inspection of your drug manufacturing facility located at 46 Mirasol St., Playa Ponce, Ponce, Puerto Rico conducted from January 14 to February 17, 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, ointment and cream drug products causing these products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. There are no Batch Production Records in accordance with 21 CFR 211.188.
2. Failure to always follow written production and process control procedures in accordance with 21 CFR 211.100 (b) in that:

Substitution of ethyl alcohol with isopropyl alcohol was made for the product ALCOHOLADO ALCANFORMENTAL 70*, lot # [REDACTED]

A sample of this product (FDA Sample # 97-747-761) was analyzed by our laboratory and was found to contain approximately 70% Isopropyl Alcohol and no trace of Ethyl Alcohol.

3. Failure to identify each batch of product with a lot or control number which permits determination of the history of the manufacture and control of the batch in accordance with 21 CFR 211.130 (c) in that:

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Labels for specific products are received with pre-printed lot numbers which are used for all batches of the product regardless of the history or date of manufacture so that all batches of the same product have the same lot number.

4. Failure to include expiration dates determined by appropriate stability testing on drug products in accordance with 21 CFR 211.137 (a) in that:

No expiration dates are placed on any drug product.

No stability testing has been performed on any drug product.

5. Failure to perform at least one test to verify the identity of each component of drug products in accordance with 21 CFR 211.84 (d) (1) in that:

All components are accepted for use based on certificates of assay from the suppliers with no sampling or testing being performed upon receipt.

6. Failure to make appropriate laboratory determination of satisfactory conformance to final specifications for each batch of drug products in accordance with 21 CFR 211.165 (a) in that:

Ointment and liniments have no finished product testing performed.

7. Failure to provide for orderly placement of materials to prevent mix-up between different labeling and drug products in accordance with 21 CFR 211.42 (b) in that:

Different finished products were stored on the same pallet

Cut labels were stored mixed all together in an unsecured cabinet

Roll labels were stored in various unprotected areas of the firm such as hallways, offices and the laboratory.

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8. Failure to have written Standard Operating Procedures for the following significant operations:

Recalls

Receipt and handling of raw materials and components
Production and process control
Packaging and labeling operations
Complaint handling
Warehousing and distribution

In addition, a sample of Alcoholado Ponce Pharma*, lot # [REDACTED] (FDA sample # 97-747-763) was analyzed by our laboratory and was found to have a specific gravity of 0.947 to 0.948 which is below U.S.P. specifications of 0.950 to 0.955, causing it to be adulterated within the meaning of Section 501 (b) of the Federal Food, Drug and Cosmetic Act.

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.

A copy of 21 CFR 211, CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS, is attached to this letter for your information.

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 00906-2332, Attention: Mary L. Mason, Compliance Officer.

Sincerely,


Samuel Jones
District Director