



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1091B

January 13, 1997

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

WARNING LETTER
CIN-WL-97-162

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Randolph A. Spoth, President
Sherwood Laboratories Inc.
1601 E. 361st Street
Eastlake, Ohio 44095

Dear Mr. Spoth:

An inspection was conducted on 12/6, 16/96 at your firm which manufactures and packages liquid topical and oral over-the-counter drugs under the Sherwood and [REDACTED] Products Brands.

The investigator documented deviations from the Current Good Manufacturing Practice Regulations For Finished Pharmaceuticals (Title 21 Code Of Federal Regulations Parts 210 & 211) which cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act (the Act). These deviations include:

- Failure to test each batch of finished drug product for identity and strength of the active ingredients.
- Expiration dates are used on the [REDACTED] brand products but no stability tests have been performed to validate them.
- Failure to prepare master formulas for some products such as Elixir Lactated Pepsin N.F., Tincture Myreh N.F., Ipsab Extra Strength and Sherwood Analgesic Cream.
- Failure to prepare written acceptance/rejection criteria for incoming components and failure to verify the reliability of Certificates of analysis upon which components are accepted.
- Failure to prepare written procedures for maintenance and calibration of equipment (scale & hydrometer); handling and storage of the finished product; complaint handling; reworking of finished products; and label accountability.
- Failure to calculate theoretical yield versus actual yield for each batch of finished product.
- Retesting for alcohol content of old components is not recorded and documented. Component use may be adjusted according to the labeled alcohol content.

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- Failure to establish time frames for which an inprocess material may be held. For example, a lot of Sherwood Analgesic Cream, produced in September 1996, was still in the mixing bowl covered with a piece of cardboard.
- Finished product stored in dirty five gallon jars with the outside coated with a gum like substance and with labels with multiple lot numbers some of which were crossed out.
- Clean pots used to cook extracts and sugar syrup for drug products were being improperly stored on the floor.

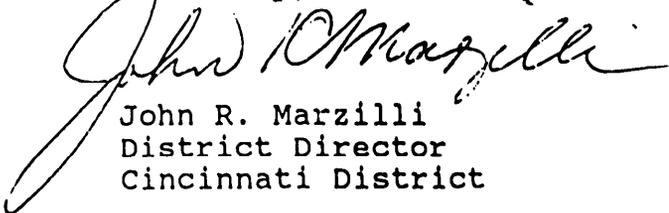
The above enumeration of deficiencies should not be construed as an all-inclusive list of violations which may be in existence concerning your drug product. It is your responsibility to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder are being met. 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.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action being initiated by FDA without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days after receipt of this letter of the specific actions you have taken to correct the violations. Your response should include (1) each step that has or will be taken to completely correct the current violations; (2) the time within which corrections will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved.

Your reply should be sent to the Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio, 45202, to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,


John R. Marzilli
District Director
Cincinnati District

LEB/clc