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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CF #1119361



Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

February 23, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Ann K. Thomas, President
Thomas & Thompson Company, Inc.
3927 Falls Road
Baltimore, Maryland 21211

Dear Mrs. Thomas:

A Food and Drug Administration (FDA) inspection was conducted from February 3 through February 8, 2000 at your manufacturing facility located in Baltimore, Maryland. The inspection confirmed that you manufacture topical salve for human use. Our review of your product determined that it is a drug as defined by Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (the Act).

During the inspection, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, processing, packing, storage or holding of drug products, are not in conformance with CGMP regulations.

The deviations include the following:

- Failure to perform appropriate laboratory testing of finished product to demonstrate conformance to final specifications prior to release. For example, no final product testing was performed on Batches #55, #56, #57, #58, #59 and #60 of Dr. Gordshell's Salve prior to release and distribution.
- Failure to establish time limits for the completion of each phase of production to assure the quality of the drug product. For example, finished product from Batch #60 has been in the mixing pot awaiting packaging since March 1998. There is no assurance that the quality of the drug has not been compromised due to the prolonged storage time.
- Failure to implement a testing program to assess the stability characteristics of drug products. For example, studies have not been performed to demonstrate the validity of the 3-year expiration date used for Dr. Gordshell's Salve.

- Failure to establish adequate batch production records for each batch of Dr. Gordshell's Salve, in that an accurate reproduction of the master production record is not being prepared for each batch. For example, Batches #56, #57, #58, #59 and #60 are all commingled on a single batch record originally prepared for Batch #56. Additionally, the weights and measures of components used in the processing of Batches #57, #58, #59 and #60 are not recorded.
- Batches are not being formulated with the intent to provide no less than 100 percent of the established ingredients. Components for drug product manufacturing are not being weighed, measured, or subdivided as appropriate. For example, unfilled drug product from Batches #56, #57, #58 and #59 were left inside the mixing pot. New batches were manufactured by adding ingredients to finished product left from the previous batch. There is no documentation of the proportional scaling, weighing and ratio of new ingredients used to manufacture Batches #57, #58, #59 and #60.
- Failure to test each lot of drug component to verify identity. For example, no identity test was performed on incoming lots of [REDACTED].
- Failure to perform appropriate laboratory testing to demonstrate that finished product is free from objectionable microorganisms.
- Failure to calibrate scales and balances at suitable intervals. For example, there were no calibration records available for the [REDACTED] used to weigh drug components.
- Failure to document cleaning of the filling machine and the mixing vessel. The last documented cleaning of this equipment was February 11, 1991.
- Failure to follow written production and process control procedures. For example, your SOP, "Procedures and Responsibilities of Quality Control Unit," dated 1/19/81, states that [REDACTED] performs testing and approval/rejection of all components. [REDACTED] is no longer being used. A change to the SOP indicates that [REDACTED] performs all testing of raw materials and finished product. [REDACTED] no longer performs any testing. No records were available to demonstrate that drug components and finished product are being tested in accordance with this procedure.
- Failure to document the examination and review of labels and to record the quantity of labels issued in batch production records.
- Failure to identify drug products with a lot or control number and expiration date.
- Failure to document the address of the consignee and lot or control number of the shipped drug product on distribution records.

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This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when considering the award of contracts. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please 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 and to prevent their recurrence. 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. Your reply should be sent to the Food & Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of David J. Gallant, Compliance Officer. Mr. Gallant can be reached at (410) 962-3461, extension 140.

Sincerely,



Lee Bowers
Director, Baltimore District

cc: Mr. John B. Thomas, General Manager
Thomas & Thompson Company, Inc.
3927 Falls Road
Baltimore, MD 21211