



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

August 4, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael L. Franchot
Chief Operating Officer
Summit Industries, Inc.
839 Pickens Industrial Drive
Marietta, Georgia 30065

WARNING LETTER

Dear Mr. Franchot:

An inspection of your drug manufacturing facility was conducted between June 9 and July 15, 1998, by Investigator Leah M. Andrews. Our inspection revealed several significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to adequately validate the manufacturing processes for any of your drug products. This failure is of particular concern for your cough and cold syrups and skin protectant products. You could not provide documented evidence which established a high degree of assurance that the manufacturing processes in use could consistently produce products meeting their predetermined specifications and quality attributes, both initially and throughout their labeled expiration date. The need to address this issue and initiate validation efforts had already been identified by your management staff.

You have failed to establish the adequacy and suitability of all in-house stock solutions used in finished product testing. You have failed to qualify your use of non-USP reference standards to prepare stock solutions. No expiration or retest dates had been established for these standards. The age of some of these standards could not be established. You have failed to establish stability data for in-house stock solutions used for HPLC analysis. The use of stock solutions greater than one year, and up to 20 months, old were noted to be used in the analysis of finished product. No records were being maintained of the preparation of these stock solutions other than what was recorded on the solution container label.

You have failed to establish the accuracy, sensitivity, specificity, and reproducibility of the HPLC test methodology currently in use. This methodology is used to test Dextromethorphan, Pseudoephedrine, Chlorpheniramine Maleate, Pyrilamine Maleate and other components. System suitability is not being performed in accordance with USP.

You have failed to implement appropriate controls to ensure that all drug components, containers, and closures have the appropriate quality and purity when introduced into production. No validation has been conducted of the water system in use. No justification could be provided for the sampling location currently in use for the ~~XXXXXX~~ microbiological sampling. No provision is made for the retesting or reexamination of components, closures, and containers on a periodic basis. Examples include a lot of Pseudoephedrine Hydrochloride and another lot of Chlorpheniramine Maleate which were used to manufacture drug products three years after their initial receipt at the firm. No additional testing is performed after initial receipt and acceptance. These components are stored in an uncontrolled environment.

You have failed to establish appropriate written procedures for all production and process controls to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. No procedures had been established for the calibration and maintenance of key analytical equipment, the investigation of out of specification results, the proper storage of laboratory standards and reagents, and the receipt and handling of raw materials.

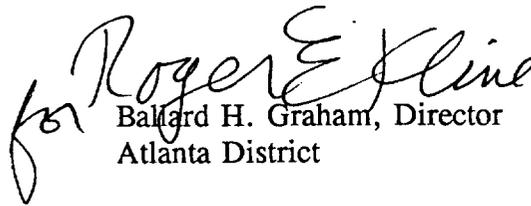
You have failed to conduct the required evaluation, at least annually, of the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. No written procedures have been established which address these periodic evaluations.

Many of the above deviations were included on the FDA 483 (Inspectional Observations) which was issued to, and discussed with, you at the conclusion of the inspection. The violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. The deviations discussed above and included on the FDA 483 should not be construed as an all inclusive list of violations which may be in existence at your firm. It is your responsibility to ensure adherence to each requirement of the Act.

You are responsible for investigating and determining the causes of the violations identified by FDA. You should take immediate actions to correct these violations. We acknowledge that some corrective action, such as the obtaining of new standards, has already been initiated. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,

for Roger E. Kline
Ballard H. Graham, Director
Atlanta District