



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

John J. Sciarra  
President  
Sciarra Laboratories, Inc.  
485-09 South Broadway  
Hicksville, New York 11801

November 1, 2000

Ref: NYK-2001-14

Dear Dr. Sciarra:

During an inspection of your drug manufacturing facility located in Hicksville, New York, conducted between the dates of September 25 and October 5, 2000, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). Such deviations cause your drug product, sterile talc powder to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. Failure to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and drug products [21 CFR 211.110(a)]. Filling operations and sealing/closing processes for sterile talc powder in vials have not be validated.
2. Failure to ensure that cleaning procedures are adequate to prevent contamination [21 CFR 211.67]. Cleaning validation is inadequate. The filling hopper is used for talc and barium sulfate products interchangeably. There is no validation data documenting that the cleaning process will ensure no cross-contamination.
3. Failure to conduct a specific identity test for active pharmaceutical ingredient talc, lot 00-002 which was used in the manufacture of intrapleural aerosol talc, and sterile talc in vials [21 CFR 211.84(d)].
4. Failure to conduct an annual evaluation of drug products by record review to determine the need for changes [21 CFR 211.180(e)].

We acknowledge receipt of Sciarra Laboratories, Inc.'s letter of October 17, 2000 responding to the Inspectional Observations (Form FDA 483) issued at the end of the inspection. We have reviewed the response and have the following comments:

Sciarra Laboratories, Inc.  
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Your timeframe for the completion of an adequate cleaning validation study by March 2001 is unacceptable. We are concerned of the potential of even low-level residue contamination of talc with barium sulfate. Validation must be completed immediately or dedicated equipment should be used.

The process validation protocol you have submitted only addresses filling. It fails to address sealing and closing operations which are important for drug products intended to be sterile for the duration of the expiratory period.

The above identification of violations and the observations on the FDA 483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. 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 award of contracts. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

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.

You should notify this office in writing, within 15 working days of the 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 similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer. Mr. Daurio's telephone number is 718-662-5585.

Sincerely,



Robert L. Hart  
Acting District Director