



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M2636 n
Food and Drug Administration
Atlanta District Office

MA-35
60 8th Street, N.E.
Atlanta, Georgia 30309

March 1, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Nelson M. Ford
President/CEO
Clinipad Corporation
175 Capital Boulevard
Rocky Hill, Connecticut 06067

WARNING LETTER

Dear Mr. Ford:

An inspection of your firm located in Charlotte, North Carolina, was conducted on February 16 & 17, 1999, by Investigator Tracy L. Ramseur. Our investigator documented 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 ointment and solution 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 appropriately validate the manufacturing processes currently utilized for any of your ointment and solution products. These include Povidone Iodine Ointment 10% USP, Acetone Alcohol, Iodophor, Povidone Iodine Solution 10% USP, Benzalkonium Chloride Antiseptic, Povidone Iodine Scrub Solution 10% USP, in addition to others. You could not provide documented evidence which established a high degree of assurance that the manufacturing processes were effective and could consistently produce a product meeting its predetermined specifications and quality attributes. Management at the Charlotte facility indicated that they understood the need to conduct appropriate validation and committed to a 9/30/99 deadline for completion of these validation activities.

You have failed to establish the adequacy of the cleaning procedures currently in use on production equipment to prevent contamination that could affect the safety, quality, or purity of your drug products. Of the ten products reviewed, only one (Rantex) had a completed cleaning validation. The Charlotte management again stated their commitment to completing this validation. We have to question your firm's commitment because the failure to have adequate cleaning validation has been discussed during our previous three inspections of this facility (May 1997, February 1993, and April 1992).

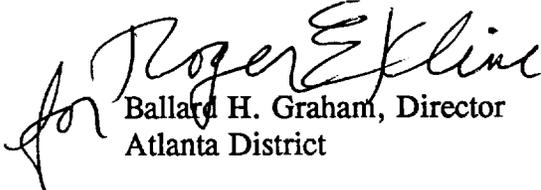
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with Dwight E. Everett, Vice President of Operations. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 could be symptomatic of underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to seizure and/or injunction.

Please notify this office in writing within fifteen (15) 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 identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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 response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Your response should also include any additional investigational work done into the cause of the recent recall of Antiseptic Towelettes, lot #814188. We are particularly interested in your final determination as to the source of the contamination, your reasoning as to the extent of the contamination problem, and an evaluation of the cause of the inadvertent release of product.

Sincerely yours,


Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Dwight E. Everett
VP, Operations
Clinipad Corporation
7101 Macfarlane Blvd.
Charlotte, NC 28262