



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m4983n

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

December 11, 2000

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Michael O. Archibong, President and CEO
Chemrich Holdings, Inc.
5211 Telegraph Road
Los Angeles, CA 90022

WL -15-01

Dear Mr. Archibong:

During an inspection of your manufacturing facility located in Los Angeles, CA conducted October 30 through November 2, 2000, an FDA investigator documented deviations from the Current Good Manufacturing Practices (cGMPs) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, (CFR) Part 211). Those deviations cause all drug products manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The violations from 21 CFR Part 211 include:

1. Failure to establish and follow control procedures to validate the performance of manufacturing processes that may be responsible for causing variability in the characteristics of the in process material and the drug product [211.110(a)]. For example, you have no written procedures for any in process tests describing how, when and where to collect samples.
2. Failure to write production and process control procedures designed to assure your drug products have the required identity, strength, quality and purity [21 CFR 211.100(a)]. For example, you have no process validation data for any of your drug products.
3. Failure to ensure that equipment used in the manufacture, processing, packing or holding of drug products is of appropriate design, adequate size, and suitably located for its intended use [211.63]. For example, you have not validated the performance of manufacturing equipment, including a lack of installation qualification, operation qualification and performance qualification of your

purified water system. Our investigator observed 4 dead legs associated with this water system.

4. Failure to follow a written testing program designed to assess the stability characteristics of drug products [211.166]. For example, you do not have a written stability testing procedure. There is no statistical criteria used to establish the sample size and testing frequency employed at your facility. Finally, you were unable to provide our investigator sufficient data to provide assurance that your drug products remain within specifications for the duration of their shelf life.
5. Failure to maintain equipment to prevent malfunctions or contamination that would alter the safety, identity, strength and purity of the drug product [211.67(a)]. For example, you have no validation that your cleaning and sanitation procedures prevent significant cross contamination from multi-use manufacturing process equipment.
6. Failure to ensure that all people engaged in the manufacture, processing, packing or holding of a drug product have the education, training and/or experience to perform their assigned functions [211.25(a)]. There is no documented cGMP training for any employees at your facility.
7. Failure to assure finished product acceptance criteria for sampling and testing is adequate to assure batches conform to specifications [211.165(d)]. For example, a single sample is taken from each finished product lot and tested for conformance to specifications.
8. Failure to prepare Master Production and Control Records designed to assure batch to batch uniformity that include all required information [211.186(b)(9)]. For example, your Master Production Records for [REDACTED] does not indicate specific mixing times or speeds.
9. Failure to establish and follow adequate laboratory controls [211.160]. For example, you do not document the calibration of your pH meter prior to testing drug products.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. 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 the award of contracts. Additionally, pending Antibiotic Form 6, New Drug Applications, Abbreviated New Drug Applications or export approval requests may not be approved until the above violations are corrected.

We acknowledge the commitment you made during the inspection to correct the previously observed deficiencies. You should be aware that we consider several of the FDA-483 observations (lack of stability indicating methods, lack of process validation,

lack of employee training, lack of written procedures) to be highly significant. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

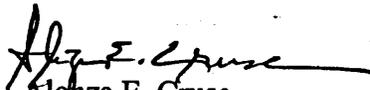
Please notify this office in writing within fifteen (15) days following the receipt of this letter, outlining the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions can not be completed within ten (10) working days thereafter, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
1990 MacArthur Blvd., Suite 300
Irvine, CA 92612.

In addition, because of the extensive nature of the above cGMP violations, we are asking you to contact this office within five (5) working days of your receipt of this letter to arrange a meeting with us to discuss this matter in person. Please be prepared to discuss the status of all products manufactured by your firm currently in distribution and to provide the District a list of all customers for whom you manufacture drug products at this meeting. You may contact the District Director's Office at 949-798-7714 to schedule this meeting.

Sincerely,


Aloha E. Cruse
District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief