



19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

WARNING LETTER

CERTIFIED MAIL

Return Receipt Requested

October 29, 2002

W/L 05-03

Charlie Ung, President  
Best Formulations  
17758 Rowland St.  
City of Industry, CA 91748

Dear Mr. Ung:

During an inspection of your pharmaceutical manufacturing facility conducted July 24 to August 7, 2002, our investigators found significant deviations from the Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 and 211). These deviations, listed below in numbered paragraphs 1-6, cause your drug products to be adulterated within the meaning of Section 501(a) (2) (B), of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 351 (a)(2)(B).

DEVIATIONS

1. Failure to perform laboratory testing on each batch of drug product prior to release, to determine satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient [21 CFR 211.165 (a)]. Specifically, you did not conduct and did not have procedures in place to conduct, finished product testing before release of the finished drug products Acetaminophen/Phenyltoloxamine tablets 500mg./50mg, Acetaminophen/Phenyltoloxamine tablets 650mg./60mg. tablets, and Hycocyanine Sulfate tablets
2. Failure to implement a written testing program designed to assess the stability characteristics of drug products, using reliable meaningful and specific test methods [21 CFR 211.166 (a)(3)]. Specifically the test method used for accelerated stability analysis of two lots of Acetaminophen/Phenyltoloxamine tablets 500mg. /50mg did not include an assessment of potential degradation products.
3. Failure to include in laboratory records complete records of the periodic calibration of laboratory instruments [21 CFR 211.194 (d)]. Specifically, there are no calibration

records available for the FTIR Spectroscope and the HPLC laboratory instruments, both of which are used in production and testing of human drugs.

4. Failure to establish control procedures which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product [21 CFR 211.110(a)]. Specifically, your firm has failed to validate the processes associated with the manufacturing of the drug products Acetaminophen/Phenyltoloxamine tablets 500mg./50mg, Acetaminophen/Phenyltoloxamine tablets 650mg./60mg. tablets, and Hycocynamine Sulfate tablets.
5. Failure to clean and maintain equipment and utensils at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product {21 CFR 211.67 (a)}. Specifically, you have failed to adequately complete the validation studies for current cleaning procedures specified for the PK Blender, and tableting equipment utilized for production of human drugs.
6. Failure to establish the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals, while accepting reports of analysis from component suppliers in lieu of testing each component for conformity with all appropriate written specifications [21 CFR 211.84(d)]. Specifically, certificates of analyses are received and used to accept Active Pharmaceutical Ingredients (API) Acetaminophen, Phenyltoloxamine, and Hycocynamine for use in production of human drug products. However, you have not verified the certificate data at appropriate intervals nor have you conducted vendor audits to validate the API suppliers, as is required by your SOP [REDACTED].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. A list of observations (form FDA-483) was issued and discussed with you at the conclusion of the inspection. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations and other applicable regulations. Federal agencies are advised of the issuance of all warning letters about drugs and medical devices 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 do so may result in regulatory action without further notice, including product seizure and/or a permanent injunction requiring you to cease manufacture of drug products. You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violation, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within (15) working days, state in writing the reason for the delay and the time within which the corrections will be completed. If you have any questions about the contents of this letter, please contact Larry Stevens, Compliance Officer, at 949-798-7732.

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Your reply should be addressed to:

Thomas L. Sawyer, Director of Compliance  
U. S. Food and Drug Administration  
19900 MacArthur Blvd, Suite 300  
Irvine, CA 92612-2445

Sincerely,

  
for Alonza E. Cruse  
District Director