



September 27, 2001

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-55-01**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Clayton Bolke, President  
American Blending and Filling  
450 Keller Drive  
Park City, IL 60085

Dear Mr. Bolke:

An inspection of your pharmaceutical manufacturing firm was conducted by our investigator on August 6, 7, 8 & 13, 2001. The inspection documented significant deviations from Current Good Manufacturing Practice (cGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These deviations cause your pharmaceutical products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding are not in conformance with cGMP regulations. These deviations include, but are not limited to the following:

- Failure of batch production and control records to include complete information relating to the production and control of each batch [21 CFR 211.188]. For example:
  - Batch records P-2111-L and P-2116-0, both for lots of Viramedx Cold Sore Treatment, do not record the actual temperatures, lengths of temperature exposure, or comparisons between the expected and actual weights as specified in the manufacturing procedures for this product.
  - Batch record A-01068-0, for the product Antibacterial Hand Gel Base, lists the batch weight as [REDACTED] pounds. The combined weight of the ingredients used in this production is [REDACTED] pounds.
  - Manufacturing equipment used in the production are not labeled or identified in the batch record.
  - The dates and times of finished product testing are not recorded on the batch record.

- Failure to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess [21 CFR 211.100(a)]. For example, your firm has no procedures for reprocessing or changing batch formulation. Reprocessing and batch formulation changes are performed without written justification as evidenced by:
  - Batch record A-01038-J, for the product Antibacterial Hand Gel, records that 4% more SD 40B 200 Alcohol was added to the mixture. There was no justification for this addition in the batch record.
- Failure to conduct adequate production record reviews [21 CFR 211.192]. For example:
  - Batch record A-01038-J, Antibacterial Hand Gel, records the first and second checks for specific gravity to be [REDACTED] and [REDACTED] where the finished product specification is [REDACTED]. Also, for this batch the specification for viscosity is [REDACTED]. Viscosity testing for this batch revealed values of [REDACTED] and [REDACTED] CPS. This lot was released.
- Failure to establish written procedures for the calibration of compounding and laboratory equipment. Instruments utilized in the manufacturing and testing of finished product are not calibrated on a routine basis [21 CFR 211.68].
- Failure to establish and follow written procedures that describe in sufficient detail the receipt, identification, storage, handling, sampling, testing and approval or rejection of drug components and drug product containers and closures [21 CFR 211.80]. For example:
  - There are no records that indicate whether incoming components are tested prior to their use in manufacturing.
  - There is no sampling plan for raw materials.
  - Records of receipt and/or certificates of analysis are not maintained for all components and raw materials for finished products.
- Failure of laboratory records to include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays in that the records fail to contain the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards [21 CFR 211.194(a)].

- Failure of laboratory controls to include written procedures for in-process testing of drug products; nor are there controls that assure that finished pharmaceutical products manufactured at this facility meet appropriate standards of identity, quality, strength and purity [21 CFR 211.160(b)].

At the conclusion of the inspection, our investigator issued the FDA-483, Inspectional Observations, to David Waldron, Vice President. A copy of the FDA-483 is enclosed.

This letter and the FDA-483 are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with the requirements of the Federal Food, Drug, and Cosmetic Act and that your pharmaceutical products are manufactured, processed, packed and held according to current good manufacturing practices. 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 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and 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 the corrections will be completed.

Please direct your response to the attention of George F. Bailey, Compliance Officer, at the address listed above.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director