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

August 24, 1999

WARNING LETTER  
CHI-31-99

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Philip Giannino, President  
Local Repack  
22327 Governors Highway  
Richton Park, IL 60471

Dear Mr. Giannino:

An inspection of your pharmaceutical repacking firm was conducted on July 7 & 12, 1999, by Investigator David Perkins. Investigator Perkins found significant deviations of the current Good Manufacturing Practice (cGMPs) for Finished Pharmaceuticals, Title 21 Code of Federal Regulations, Part 211 (21 CFR 211). The inspection disclosed that your firm's repacked drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviations observed during the inspection included:

Failure of master production and control records to include complete information, along with failure to establish and follow written procedures that describe the preparation of master production and control records. For example, master records do not include a description of the containers and closures to be used for each specific product nor was a specimen or copy of each label and all other labeling signed and dated by a person responsible for approval of such labeling. [21 CFR 211.186(a), (b)(8)]

Failure to ensure that each person engaged in the manufacture, processing, packing, or holding of a drug product has the education, training, and experience to enable that person to perform the assigned function. The inspection revealed that employees responsible for the repacking operations have not received any training in current good manufacturing practice or in the operations they are required to perform in the repacking operation. [21 CFR 211.25(a)]

Failure to follow written procedures for production and process control designed to assure that the drug products have the strength, quality, and purity they purport or are represented to possess. For example, your firm's procedure entitled "Standard Operating Procedures A.W.D. Division" (SOP), which was signed by you on November 1, 1996,

requires that reserve samples of repacked drugs be collected and maintained. The inspection found that reserve samples have not been maintained since March 1997. This SOP also requires that shipments of in-coming containers and closures be entered into a bottle and closure inventory book. The inspection revealed that these requirements are not being performed. [21 CFR 211.100(a)]

Failure to maintain a record of maintenance, cleaning, sanitizing and inspection of the [REDACTED] that is the only counter used by your firm in the repacking operations. [21 CFR 211.65(c)]

Failure to establish a quality control unit that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. [21 CFR 211.22]

Failure to establish written procedures that describe the distribution of drug products. [21 CFR 211.150]

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 cGMPs. Federal agencies are advised of the issuance of all Warning Letters about drugs and 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 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 receipt of this letter, of 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 the delay and the time within which corrections will be completed. Your response should be addressed to the attention of Compliance Officer George F. Bailey at the address indicated in the letterhead.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director