



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Detroit District Office
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-10

February 17, 2000

Mason Goodman, M.D.
Chief Executive Officer/President
Pharmaceutical Corporation of America
12348 Hancock Street
Carmel, IN 46032

Dear Dr Goodman:

Investigators Patricia Cochran, David Duncan and Neal Singletary conducted a limited inspection of Pharmaceutical Corporation of America (PCA) repackaging operations as a follow-up to a labeling mix-up from December 2-17, 1999. The focus of the inspection was to determine how the mix-up occurred as well as where the firm's quality systems failed in allowing the release of misbranded product. They found your firm to be operating with significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products. Accordingly, the drugs repackaged by PCA are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act in that the controls used for the manufacture, processing, packaging or holding of the products are not in conformance with Title 21 CFR 210 and 211.

- 1 Failure to adequately examine drug product labeling before use in that Tetracycline 500 mg capsule labels for lot S298QJ contained the bar code for Carbamazepine Tablets [211.122(a)]
- 2 Failure to adequately examine labeling for a batch in that at least [REDACTED] labels issued for the packaging of Carbamazepine Tablets lot S302QJ were in fact Tetracycline Capsule lot S298QJ labels.[211.125 (a)&(b)]
- 3 Failure to reconcile the quantities of labeling issued, used, and returned in that employees reportedly destroy all excess labels and enter the number ten on the batch record regardless of the number destroyed. [211.125(c), 211.184 & 211.188]
- 4 Failure to adequately examine packaged and labeled product during finishing operations to provide assurance that containers and packages in the lot have the correct label in that at least [REDACTED] bottles of Carbamazepine Tablets lot S302QJ were labeled and distributed as Tetracycline Capsules lot S298QJ.[211.134]
- 5 Failure to have a Quality Control Unit adequate to perform its functions and responsibilities as demonstrated by the number and types of inspectional observations. [211.22]
- 6 Failure to assure that each person engaged in and each person responsible for supervising the manufacture and processing of drug products has the education, training, or experience to enable that person to perform his or her assigned functions. [211.25 (a) & (b)]

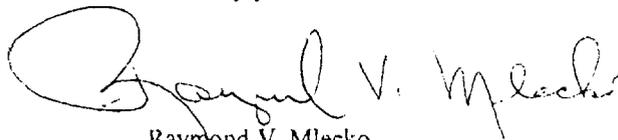
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. We request that you take prompt action to correct these deficiencies and to ensure that your drug repackaging operations are in full compliance with the Act and regulations promulgated thereunder. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

We acknowledge receipt of your December 29, 1999 and January 14, 2000 written responses to the list of inspectional observations as well as your commitments to take specific steps to both correct the noted violations, and to make systemic corrections to assure that similar violations will not recur. We concur in your decision to seek the assistance of outside expertise to make the necessary corrections. We also acknowledge that you voluntarily shut the repackaging operations down from December 6, 1999 to January 5, 2000 and recalled Carbamazepine Tablets lot S302QJ and Tetracycline Capsules lot S298QJ.

Your responses, however, are silent with respect to your assessment of the product on hand on December 6, 1999 as well as the product in distribution channels. The deficiencies encountered in your quality control systems were serious. The fact that you repackaged and labeled an array of prescription drugs with labels of similar size, shape, and color with questionable control is a real concern. Given that our Investigators and your staff were unable to determine exactly how the Carbamazepine mix-up occurred, there seems to be little assurance that another label mix-up would have been identified before product release. Please notify this office in writing, within 15 working days of receipt of this letter, of your assessment of the product on hand on December 6, 1999 and product in distribution channels. Any additional steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations should be included. If additional corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Any additional correspondence should be directed to the Food and Drug Administration, attention Mrs. Judith A. Putz, Compliance Officer at the above address.

Sincerely yours,



Raymond V. Mlecko
District Director
Detroit District