



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g1632d  
Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

August 17, 2001

**VIA FEDERAL EXPRESS**

Mr. Joel Stewart, Owner  
Stewart-Jackson Pharmacial Inc.  
4587 Damascus Road  
Memphis, TN 38118

**Warning Letter No. 01-NSV-37**

Dear Mr. Stewart:

During an inspection of your own-label drug distribution facility on July 18, 2001 our investigator documented violations of the Current Good Manufacturing Practice Regulations (CGMPs), Title 21, Code of Federal Regulations, Part 211. These violations cause your strip-packaged drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

**[REDACTED]**, strip-packages seven (7) drug products under contract with your firm whereby you retain responsibility for the product stability testing program. Our inspection revealed that you have no stability data to support the expiration dates applied to the strip-packaged drug products.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Current Good Manufacturing Practice Regulations. Until these violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

You should take prompt action to correct these violations. 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 fifteen (15) working days of receipt of this letter of 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 action cannot be completed within 15 working days, state the reason for the delay and time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217, Attention: Joseph E. Hayes, Compliance Officer.

Sincerely,



Carl E. Draper  
Director, New Orleans District

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Enclosures:

21 CFR 211  
FDA Form 483

cc: Sue Andrews  
Office Manager  
Stewart-Jackson Pharmacial Inc.  
4587 Damascus Road  
Memphis, TN 38118