



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9 41500
Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5388
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July 18, 2003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Robert L. Allen, President
PrePak Systems, Inc.
3077 Poplar Grove Road
Cookeville, Tennessee 38501

Warning Letter No. 03-NSV-18

Dear Mr. Allen:

During an inspection of your facility on April 15-21, 2003, our investigators documented violations of the Current Good Manufacturing Practice (CGMP's) regulations, Title 21, *Code of Federal Regulations*, Part 211. These violations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that the prescription drug products repackaged by your firm fail to bear an appropriate expiration date to assure that these repackaged drug products meet applicable standards of identity, strength, quality and purity at time of use. [21 CFR 211.137]

Your firm assigns to its repackaged prescription drug products the expiration date that appears on the labeling of the original manufacturer's container from which the drugs are repackaged. Yet, your firm fails to have adequate data demonstrating that the containers used by your firm for its repackaged drug products are equivalent or superior to the original manufacturer's containers from which the drugs are repackaged, in terms of their protective properties. Your response does not include any information comparing the moisture permeation characteristics of the polypropylene containers used by your firm for repackaging with those of the original manufacturer's high-density polyethylene (HDPE) containers. The absence of such comparative moisture permeation data is a serious deficiency in your data. Additionally, your firm does not package its drug products with a desiccant even when the original manufacturer's product is packaged with a desiccant for moisture sensitive drug products. Considering the absence of such data showing container-closure equivalency, and the failure to use a suitable desiccant in repackaged bottles when the original manufacturer's bottle contains a desiccant, it is inappropriate to assign the manufacturer's expiration dating to your repackaged bottles.

Your response to Form FDA 483 observation 3, concerning master label controls, indicates that your firm now maintains a signed and dated master label for each product that it repackages. We note, however, that the sample copy provided with your response is not dated. Your failure to have appropriate procedures for maintaining master labels for each product is a violation of 21 CFR 211.186(b)(8).

Your response to Form FDA 483 observation 6, concerning the lack of specifications for drug product containers and closures used for repackaging, does not specify whether there are written specifications approved by the firm's quality control unit for each different container-closure used by the firm.

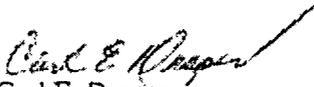
The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Current Good Manufacturing Practice regulations. Until the violations are corrected, federal agencies will be informed that the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

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in FDA initiating regulatory action, including seizure and/or injunction, without further notice.

Please 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 corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,


Carl E. Draper
Director, New Orleans District

CED:JEH:ss

Enclosure:

21 CFR Part 211

FDA Draft Guideline on Repackaging Solid Oral Dosage Form Drug Products