



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

January 12, 1999

Completed
1/14/99
JDA

REGISTERED-RETURN RECEIPT REQUESTED

Mr. Edgar D. Bryson, President
Rural Health Service Consortium, Inc.
4966 Highway 11 West
Surgoinsville, TN 37873

Dear Mr. Bryson:

WARNING LETTER - 99-NSV-04

During an inspection of your repackaging facility on December 8 and 10, 1998 our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations 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 the repackaging of penicillin products without separation from other products, a lack of stability data to support expiration dates on liquids, semi-solids and product mixtures, failure to show that container/closure systems for repackaged solid dosage drugs support expiration date, inadequate and incomplete Standard Operating Procedures, failure to document that returned drugs are suitable for redistribution, incomplete master production and control records and inadequate label control.

The inspection also revealed that your facility was not currently registered with the Food and Drug Administration. Therefore the products repackaged by you are misbranded under Section 502(o) of the Act in that they are repackaged in a facility that is not duly registered under Section 510 of the Act. Your repackaged drug products also have not been listed as required by Section 510(j) of the Act. We are enclosing registration and listing forms for your use.

Some of your repackaged products may also be misbranded under Section 502 of the Act in that their labels lack directions for use, listing of product ingredients, and warning statements from

Mr. Edgar D. Bryson, President - Page 2

the manufacturers label. We are enclosing 21 CFR Part 201 for your use in labeling your repackaged products.

The above identification of violations is not intended to be an all-inclusive list of problems at your firm. It is your responsibility to ensure adherence to all requirements of the Act. Until 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 violations 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 fifteen (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,



Howard E. Lewis, Acting Director
Nashville District

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Enclosures:

21 CFR Parts 210 and 211
21 CFR Part 201
Form FDA-2656 - Registration of Drug Establishment
Form FDA-2657 - Drug Product Listing
Instruction Booklet

cc: Kendall Lynch, Director
TN Board of Pharmacy