



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g1202d Public Health Service JEH
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

April 10, 2001

VIA FEDERAL EXPRESS

Mr. Glenn D. Baird, President
Classic Care Products, Inc.
dba/The River City Company
809 Market Street
Chattanooga, TN 37405

Warning Letter No. 01-NSV-23

Dear Mr. Baird:

During an inspection of your veterinary drug manufacturing facility on March 20 and 22, 2001 our investigator documented deviations from the Current Good Manufacturing Practice Regulations (CGMPs), Title 21, Code of Federal Regulations, Part 211, which cause your veterinary drugs 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 no component testing, no master production records, incomplete batch production records, failure to conduct stability studies on finished products and to assign expiration dates based on these studies, no label controls, no cleaning and maintenance records for manufacturing equipment, and failure to follow Standard Operating Procedures.

Veterinary drug products manufactured by your firm are also misbranded under Section 502(o) of the Act in that they were manufactured in an establishment that was not registered under Section 510 of the Act and your veterinary drugs have not been listed as required by Section 510(j) of the Act. We are enclosing forms for you to register your establishment and list your products.

Our investigator also determined that the ingredient statement on your "Black Salve" and "Sulfur Ointment" products do not agree with the formulation of the products. The labeled ingredient statement for these products should accurately reflect the ingredients in the product.

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You should be aware that you are responsible for assuring that your firm operates in compliance with the law. Should you continue your veterinary drug manufacturing operations, you must register your firm as a Drug Establishment, list your veterinary drug products, and fully comply with the Current Good Manufacturing Practice regulations.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. Until the 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 deviations. Failure to promptly correct these deviations may result in 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, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,


Carl E. Draper
Director
New Orleans District

JEH/kl

Enclosures:

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