



DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION  
4298 Elysian Fields Avenue  
New Orleans, LA 70122-3896  
Telephone (504) 589-7166  
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SSA

August 22, 1997

WARNING LETTER NO. 97-NOL-58

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Dr. Richard A. Knutson, Chairman  
Wide River Chemical Company  
Post Office Box 633  
Greenville, Mississippi 38701

Dear Dr. Knutson:

During an inspection of your firm on July 1 through July 2, 1997, our investigator documented deviations from the Current Good Manufacturing Practices Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). These deviations cause your product, Sugardyne Skin Wound Protectant, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

These deviations included no finished product testing since August 1996; no raw material testing performed, including active ingredient testing on receipt, before use or after prolonged storage; no temperature or humidity monitored in any of the firm's areas, including production, raw material and finished product storage; no validation of cleaning and production processes; no stability data available for review on products manufactured since 1993; and finished product batch records were not available for review.

In addition, you informed us that your product was analyzed after the inspection and the results were within the product's specifications. Please send a copy of the lot numbers tested and the analytical data and calculations so that we may review these results.

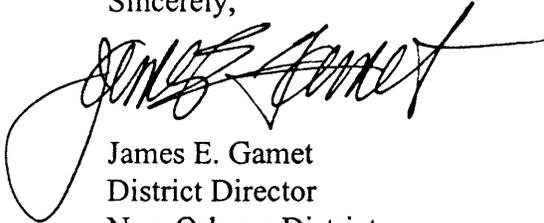
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Until these violations are corrected, federal agencies will be informed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

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

You should notify this office in writing, within 15 days of receipt of this letter of the 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 can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Ms. Olsen at telephone number (504) 589-7166.

Sincerely,



James E. Gamet  
District Director  
New Orleans District

Enclosures: FDA-483  
21 CFR 210  
21 CFR 211

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