



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
D1371B

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

February 4, 1998

Ref: 98-DAL-WL-15

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

J. Rao Nulu, Ph.D.  
President and Owner  
Trinity Chemical Corporation  
130 West Rhapsody  
San Antonio, Texas 78216

Dear Dr. Nulu:

During an inspection of your drug manufacturing facility on January 12 and 14, 1998, our investigator documented deficiencies from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). The deficiencies noted during the inspection cause your drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

1. Failure to perform process validation on drug manufacturing processes.
2. Failure to perform stability studies on BioFlexor Gel to justify the two year expiration date.
3. Failure to collect a representative sample of BioFlexor Gel for finished product testing.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. A complete list of observations (FDA-483) was issued to you and discussed with you at the close of the inspection. It is your responsibility to assure that your facility is in compliance with all requirements of the federal regulations. Please address each deviation listed on the FDA-483 in your written response and not just the citations in this letter.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

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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 deviations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. A copy of this letter is being sent to Health Care Laboratories, Inc., Houston, Texas.

Your reply should be sent to the attention of Ms. Gwendolyn S. Gilbreath, Compliance Officer, at the above letterhead address.

Sincerely,

  
for Joseph R. Baca  
Dallas District Director

JRB:GSG

cc: Larry D. LaBove, R.Ph.  
President  
Health Care Laboratories, Inc.  
15116 Lee Rd. Suite 508  
Houston, Texas 77369