



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

February 28, 2003

VIA FEDERAL EXPRESS-NEXT DAY

Mr. Jeff Bedard
CEO and Chairman of the Board
Crown Laboratories Inc.
2301 Buffalo Road
Johnson City, TN 37605

Warning Letter No. 03-NSV-11

Dear Mr. Bedard:

During an inspection of your facility on January 7-14, 2003, our investigator documented violations of the Current Good Manufacturing Practice Regulations (CGMPs), Title 21, Code of Federal Regulations, Part 211. These violations cause your drug products to be adulterated with the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed no cleaning validation for drug products or equipment 21CFR§211.67(b), inadequate sampling and testing of components 21CFR§211.80 and 211.84, inadequate product process validation, including the water system 21CFR§211.110, inadequate labeling procedures 21CFR§211.122, inadequate finished product testing 21CFR§211.165(d), inadequate stability testing 21CFR§211.166, incomplete master production and control records 21CFR §211.186, incomplete batch production and control records 21CFR§211.88 and inadequate complaint procedures 21CFR§211.198.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Current Good Manufacturing Practice Regulations and to correct the violations noted in this letter and the Form 483 issued at the conclusion of the inspection.

Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending NDA, ANDA, or Certificates to Foreign Governments requests will not be approved until the above violations are corrected.

We acknowledge your response of January 24, 2003 to our investigators' observations noted on the Form FDA 483. However, we need additional information in that your response did not contain details of how your plan to accomplish the promised corrections and a time frame of one year to correct some of the deviations is unacceptable. Examples include verification of certificate of analysis, water testing and validation, label controls, anti-microbial effectiveness testing on your Ulcerease Products, stability testing of your Blue Lizard products and corrections of master and batch records.

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

You should notify this office in writing within fifteen (15) working day of receipt of this letter of the specific steps, your 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 the time within which the corrections will be completed. Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:ss

Enclosure:

21 CFR Part 211

cc: Don Kilday
Executive VP, Secretary and Treasurer

John Deloach
VP Regulatory Affair