



June 24, 1998

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-28-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lawrence F. Schneider, President
First Priority, Inc.,
1588 Todd Farm Drive
Elgin, IL 60123

Dear Mr. Schneider:

During an inspection of your manufacturing facility, conducted from April 27, through May 5, 1998, FDA Investigator Nicholas Lyons documented serious deviations from the Current Good Manufacturing Practice Regulations (CGMP), Title 21, Code of Federal Regulations, Part 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 deviations included:

Failure to exercise strict control of labeling issued for use in drug product labeling operations. For example: On 4/28/98, Investigator Lyons observed that approximately one foot from the labeling operation for the product, Priority Care Blue Lotion Topical Antiseptic, Lot #A10, labels for several products including, Iodine Tincture 7%, Isopropyl Alcohol 99%, Mineral Oil, and Anti Bacterial Hand Soap were observed in the labeling area. Investigator Lyons also observed that the labeling form for Lot #A10 Blue Lotion Topical Antiseptic contained the verification by an employee that this labeling area was free of all other labels at the time the labeling operation was performed.

Failure to establish and follow written procedures designed to assure that correct labels, labeling and packaging materials are used. For example, there were no written procedures which address the examination of packaging and labeling materials for suitability and correctness before packaging operations.

Failure to establish and follow written procedures that describe in sufficient detail the control procedures to employ for the issuance of labeling. For example, Investigator Lyons reported that he observed that the QC label form section entitled "Quality Check Visual-each container" were being signed by employees indicating that the labeling of a lot was completed and that a label was placed on each container. Investigator Lyons reported that for at least ten lots, which included Organic Iodine Lot #E1Q, Iodine Tincture Lot #E1Q, Povidone Iodine Ointment Lot #C10 and Bismusol Lot #C10, employees signed this section of the

form before the labels had been picked from the label room inventory and prior to the actual labeling operation. Investigator Lyons also observed that the section of the Label Form in which an employee verifies that the labeling area was free from all other product labels is signed by an employee before the labels are taken from the labeling room and prior to the labeling operation.

Failure to validate the water system used to produce purified water, a component in drug formulations.

Failure to establish bacteriological specifications for water used as a component for drug formulations.

Water was observed leaking at the bottom elbow of the 4,400 gallon storage tank used to hold purified water.

Failure to hold lots from distribution before the production records have been reviewed and released by Quality Control (QC). For example, Investigator Lyons reported that the following products were released by QC and distributed before finished product testing was completed: Chlora-Dip Lot #A10, Chlorhexidine Scrub Lot #B10, Chlorhexidine Scrub Lot #L1P, Blood Stop Powder Lot #B30 and Corti-Derm Cream Lot #G1P.

Batch Records are approved by QC as meeting specifications prior to the finished product being assayed by the control testing lab. Examples of this practice are listed in the aforementioned section.

Failure of the drug master records and all drug batch records to contain minimum and maximum specifications for theoretical product yield.

Failure to establish a procedure to quarantine finished products while finished product testing is being performed.

Failure to assess the stability characteristics of Chlorhexidine Gluconate. Investigator Lyons reported that your firm has changed several of your formulations for 2% Chlorhexidine Gluconate. There have been no studies performed which determine if the changes effect the quality and purity of the newly formulated products.

This letter, as well as the Form FDA 483, is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with the requirements of current Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

page 3

We acknowledge receipt of your response dated May 18, 1998, to our Form FDA 483. In your response you indicate that several SOPs have been drafted and you provided target dates for the implementation of the SOPs and the training of your personnel. Copies of the new SOPs were not provided so we have no additional comment to make other than to say that the content of the SOPs and the question of whether they are being followed by your personnel will be addressed during our next inspection.

Please notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to prevent future violations, including an explanation of each step being taken to prevent the recurrence of the violation. You may reference your May 18, 1998 letter in your response.

Your response should be sent to the attention of George F. Bailey, Compliance Officer.

Sincerely,



Raymond V. Mlecko
District Director