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Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

April 24, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER
KAN #2000-015

Kent A. Misemer, Chief Executive
Officer
York Pharmaceutical, Inc.
1201 Douglas Avenue
Kansas City, KS 66103

Dear Mr. Mismer:

Recently an inspection was made of your over-the-counter (OTC) drug manufacturing operation at the above address. This inspection was conducted on March 20 to April 7, 2000, by a Food and Drug Administration Investigator and Chemist from this office who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the OTC drugs manufactured at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

- Failure to have written equipment cleaning procedures in place to assure that production equipment is protected from potentials for contamination [21 CFR 211.67]. Examples include:

No approved sanitizing procedures in use when production of antacid products began in March 1999.

No validated cleaning procedures for various equipment systems such as the homogenizer and pasteurizer.

Observation of employee practices during vessel cleaning which could lead to contamination of the vessel.

Observations of post-cleaning manufacturing residue in tank #6.

Observations of potential vessel contamination from pooled or standing water sites.

- Failure to complete process validation on milk of magnesia and liquid antacid products prior to release for distribution [21 CFR 211.110 & 211.113(a)]. Examples include:

Not less than [REDACTED] batches of milk of magnesia were manufactured and released prior to completion of validation on 10-27-99.

Not less than [REDACTED] batches of fast acting liquid antacid were manufactured and released prior to completion of validation on 10-22-99.

Not less than [REDACTED] batches of liquid antacid were manufactured and released prior to completion of validation on 10-22-99.

At least [REDACTED] batches of bismuth liquid have been manufactured and released, yet validation was not complete at the time of the inspection.

- Failure to place milk of magnesia and liquid antacid products on a stability program prior to releasing manufactured product for distribution [21 CFR 211.166(b)]. Examples include:

Release of milk of magnesia batches beginning 3-25-99; product placed on stability 11-1-99.

Release of at least [REDACTED] batches of regular strength liquid antacid prior to initiating stability testing on 9-28-99.

Release of at least [REDACTED] batches of extra strength liquid antacid prior to initiating stability testing on 9-30-99.

Release of at least [REDACTED] batches of single strength liquid antacid prior to initiating stability testing on 10-16-99.

- Failure to confirm the reliability of supplier's raw material analyses through appropriate validation of the supplier's test results at appropriate intervals [21 CFR 211.84(d)(2)].
- Failure to perform complete monograph testing for currently marketed liquid antacid and milk of magnesia compendial products [21 CFR 211.165(e)].
- Failure to follow firm's Standard Operating Procedures (SOP) for reviewing and investigating occurrences of products found to be out of specifications [21 CFR 211.192 and 211.188(b)(12)].
- Failure to record specified information in batch production records, and failure to adequately review batch production records [21 CFR 211.188(b) and 211.192]. Examples include:

Not reviewing pasteurizer recording charts prior to batch release of liquid antacid products.

No instructions in manufacturing records on how to initiate the pasteurization process.

No recording of times that finished product samples are collected.

- Failure to have written procedures for, and failure to perform annual product reviews [21 CFR 211.180(e)]

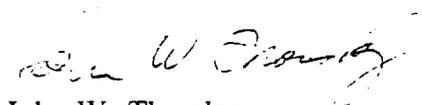
The above is not intended to be an all-inclusive list of violations. As a manufacturer of drug products, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with you. This form is a comprehensive listing of the investigators' observations of deviations found during the inspection. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your drug products. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



John W. Thorsky
Acting District Director
Kansas City District

cc: Patrick J. Lais, President
and Chief Operating Officer
York Pharmaceutical, Inc.
1201 Douglas Avenue
Kansas City, KS 66103