



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: CFN 1117263

HFF-BBS

Public Health Service

M3230n

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461 x122
FAX: (410) 962-2219

November 30, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas L. Johnson, President
The Heritage Store, Inc.
314 Laskin Road
Virginia Beach, Virginia 23451

Dear Mr. Johnson:

A Food and Drug Administration (FDA) inspection was conducted October 21 - November 12, 1999 at your facility in Virginia Beach, Virginia. During the inspection, it was determined that you manufacture Atomidine, a drug product as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the current Good Manufacturing Practice (cGMP) regulations (Title 21, Code of Federal Regulations, Parts 210 and 211) were observed. These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding, are not in conformance with the cGMP regulations.

The cGMP deviations observed during our inspection include, in part, the following:

1. Failure to establish a quality control unit.
2. Failure to establish and follow written procedures describing the responsibilities and procedures for the quality control unit.
3. Failure to follow written production and process control procedures and/or to record/justify deviations from these procedures.
4. Failure to prepare batch production and control records for each batch of drug product manufactured to document that all significant steps in the manufacture, processing, packaging, or holding of the batch were accomplished.
5. Failure to establish and follow a written testing program designed to assess the stability characteristics of drug products.

6. Failure to test an adequate number of batches of each drug product to determine an appropriate expiration date and to maintain a record of such data.
7. Failure to assure that all drug product production and control records, including those for packaging and labeling, are reviewed by the quality control unit to determine compliance with established, approved written procedures before a batch is released or distributed. Failure to investigate any unexplained discrepancies or the failure of a batch to meet any of its specifications, and to keep a written record of the investigation that includes conclusions and follow-up.
8. Failure to maintain records for all components for the designated length of time.
9. Failure to maintain a written record of major equipment cleaning, maintenance and use.
10. Failure to maintain records for each shipment of different labeling material received, indicating receipt, examination, or testing, and whether the labeling material was accepted or rejected.
11. Failure to establish procedures to reconcile the quantities of labeling issued, used, and returned, and to evaluate discrepancies found between the quantity of finished drug product and the quantity of labeling issued.
12. Failure to establish and follow written procedures describing the handling of written and oral complaints regarding a drug product.
13. Failure to maintain a written record of each complaint in a file designated for drug product complaints.

This letter 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 Act and federal regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you during the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA and promptly initiating permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters concerning drugs so that they may take this information into account when considering the award of contracts or when issuing certificates of export.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including the timeframe within which the corrections will be completed. Corrective action plans should also indicate the person responsible for effecting the correction and include any supporting documentation indicating that correction has been achieved. If

Mr. Thomas L. Johnson
November 30, 1999
Page 3

corrections cannot be completed within 15 working days, state the reason for the delay and the timeframe within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

A handwritten signature in cursive script that reads "Roberta F. Wagner".

Roberta F. Wagner
Acting Director, Baltimore District