



DEPARTMENT OF HEALTH & HUMAN SERVICES

m 26987

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 9, 1999

Kenneth K. Lee
President
Generic Sal, Inc.
300 Corporate Drive
Blauvelt, NY 10913

Ref: NYK 1999-047

Dear Mr. Lee:

During our March 23 through April 9, 1999 and May 14 through 17, 1999 inspection of your facility located in Blauvelt, New York, our investigator documented deviations from Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause drug products manufactured by your firm, such as Senna-C Plus Tablets, Senna-Lax Tablets and Gentle Woman's Laxative Tablets, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) as follows:

1. Failure to validate the performance of those manufacturing processes, such as drying and coating, that may be responsible for causing variability in the characteristics of in-process materials and drug products.
2. Failure to validate the cleaning of equipment used in the manufacture of drug products.
3. Failure to establish the reliability of component supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.
4. Failure to have a written testing program designed to assess the stability characteristics of drug products.
5. Failure to record and justify deviations from written specifications for the coating process of drug products. For example, not all of the coating materials listed in the specifications sheet were used in the coating of Bisacodyl-Lax Tablets.
6. Failure to have separate or defined areas or other control systems for the packaging and labeling operations to prevent contamination or mixups.

Generic Sal, Inc.
Page 2

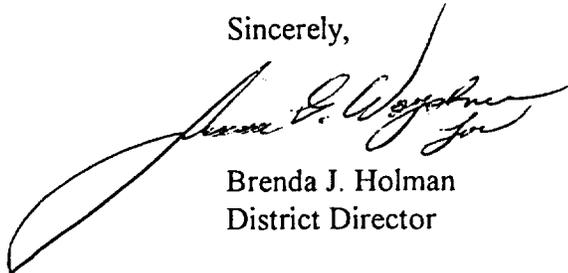
The violations of the Act described above are not meant to be an all-inclusive list of deficiencies by your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with the Act. Federal agencies are advised of the issuance of all warning letters about drugs so they may take this information into account when considering the award of contracts.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to prevent 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 corrections will be completed.

You should send your reply to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Fabio L. Mattiasich, Compliance Officer. If you have any questions regarding the content of this letter, Mr. Mattiasich can be reached at (718) 340-7000, ext. 5292.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman". The signature is fluid and cursive, with a large loop at the end.

Brenda J. Holman
District Director