



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3272N

DEC 20 1999

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Brian T. Fitzpatrick
President and Chief Executive Officer
H. B. Gordon Manufacturing Co., Inc.
751 East Artesia Boulevard
Carson, CA 90746

W/L 16-00

Dear Mr. Fitzpatrick:

During an inspection of your manufacturing facility located at 751 East Artesia Boulevard, Carson, CA, conducted October 5 through 7, 12, and 28, 1999, an FDA investigator documented deviations from the Current Good Manufacturing Practices (cGMPs) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, (CFR) Part 211). Those deviations cause all drug products manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The violations from 21 CFR Part 211 include:

1. Failure to establish production and process control procedures designed to assure your drug products have the required identity, strength, quality and purity [21 CFR 211.100(a)]. For example, you have no process validation procedures for any of your OTC drug products nor have you validated the performance of process equipment. Examples of non-validated process equipment include your deionized water system, compounding tanks, mixers and filling machines used in the production of your OTC drug products.
2. Failure to maintain equipment to prevent malfunctions or contamination that would alter the safety, identity, strength and purity of the drug product, failure to establish and follow appropriate written procedures [211.67(a) and (b)]. For example, you have no validation that your cleaning and sanitation procedures prevent significant cross contamination of drug products that could arise from multi-use manufacturing process equipment.

3. Failure to maintain and follow written procedures that describe the receipt, identification, storage, handling, sampling examination and/or testing of labeling [211.122(a)].
4. Failure to store labels and labeling material for each different drug product separately with suitable identification and in a storage area with access limited to authorized personnel [211.122(d)]. For example, labels for several different drug products were stored together on an open shelf accessible to unauthorized personnel.
5. Failure to destroy outdated labels [211.122(e)]. For example, labels for an outdated product were observed in the label storage area.
6. Failure to maintain equipment at appropriate intervals to prevent malfunctions that would alter the safety, identity, strength, quality or purity of the drug product [211.67(a)]. For example, balances used in drug manufacturing lacked calibration verification.
7. Failure to provide employees adequate hand washing facilities [211.52]. For example, restroom facilities were observed without air dryers or single service towels available.
8. Failure to maintain your facility in a good state of repair [211.58]. For example, holes were observed in the outside wall of the drug processing area.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your Carson, CA facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. 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 Antibiotic Form 6, New Drug Applications, Abbreviated New Drug Applications or export approval requests may not be approved until the above violations are corrected.

We acknowledge the corrections you made during the inspection to correct some of the observed deficiencies. However, you should be aware that we consider several of the FDA-483 observations (lack of process validation, lack of label control and lack of label control procedures) to be highly significant. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

In addition, we offer the following comments:

You have not updated the listing of drug products manufactured at your facility as required by 21 CFR 207.20 and 207.21. It is your responsibility to either list the products with FDA or receive certification from the owner of the drug products (including Form FDA-2656) that he has listed the products.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you 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 corrections will be completed.

Your written response should be directed to the Food and Drug Administration,
Attention:

Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,



Thomas L. Sawyer
Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief