

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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Refer to: CFN 1121655

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4017

November 27, 1996

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Christopher A. Roberts, General Manager  
Giant Repacking Center  
7100 Ambassador Road  
Baltimore, Maryland 21244

Dear Mr. Roberts:

During an inspection of your drug repacking facility located in Baltimore, Maryland, conducted by the Food and Drug Administration from November 5 through November 15, 1996, our investigator documented deviations from the current Good Manufacturing Practice (cGMP) regulations (Title 21, Code of Federal Regulations, Parts 210 and 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 as follows:

1. Failure to quarantine drug products prior to release by the quality control unit [21 CFR 211.142(a)].
2. Failure to establish acceptance criteria for actual yield [21 CFR 211.103].
3. Failure to establish adequate written procedures for in-process testing, in that your procedure does not specify the frequency of testing [21 CFR 211.110(a)].
4. Failure to establish written procedures for reprocessing of drug products that fail to conform to in-process testing specifications [21 CFR 211.115(a)].
5. Failure to establish written procedures for the disposition or reworking of returned drug products [21 CFR 211.204].
6. Failure to ensure that drug products are stored under appropriate conditions of temperature and humidity so that the identity, strength, quality, and purity of the drug

products are not affected, in that (1) your firm has not determined that the temperature/humidity equipment used to monitor the storage area is adequate to monitor the entire area; (2) the monitor is not equipped with an alarm to alert your firm to environmental control failures; (3) your firm has no written procedure for calibration of the temperature/humidity monitor and does not follow the manufacturer's specifications for calibration of the monitor [21 CFR 211.46(b), 211.142(b)].

7. Failure to have procedures which fully describe the calibration of equipment, including the counting unit, cotton inserter, capper, labeler, and induction cap sealer [21 CFR 211.68(a)].
8. Failure to follow your firm's procedure for sampling drug products, in that finished drug products are not sampled. In addition, your firm does not perform any testing on the finished drug products [21 CFR 211.165(a), (c)].
9. Failure to examine reserve samples of finished drug products for deterioration [21 CFR 211.170(b)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the cGMP 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, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should 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 an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

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Your reply should be directed to the Food and Drug Administration, Baltimore District Office,  
900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Jennifer Thomas,  
Compliance Officer.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth C. Shelin". The signature is written in black ink and is positioned above the printed name and title.

Kenneth C. Shelin  
District Director

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bcc: 1IFI-35 (purged)  
HFA-224  
HFC-210  
HFD-300  
HFC-240  
HFC-120  
HFR-MA200  
HFR-MA250 (Simmons, Weidman)  
HFR-MA295  
EI file  
Legal file

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