



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HFI-35

m49517

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

December 5, 2000

Ref: 2001-DAL-WL-06

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Mark Boyd, Acting President/CEO
Control Solutions, Inc. DBA C.J. Martin
2739 Pasadena Boulevard
Pasadena, TX 77502

Dear Mr. Boyd:

During inspections of your veterinary drug manufacturing facility located at Pasadena, TX, conducted on August 4-8 and October 18, 2000, our investigator found significant deviations from the Current Good Manufacturing Practice (CGMP's) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 210 and 211). Such deviations cause your veterinary drug products to be adulterated within the meaning of Section 501(a)(2)(B), of the Federal Food, Drug, and Cosmetic Act (the Act).

At the conclusion of the August 4-8, 2000, inspection, an FDA-483 (List of Inspectional Observations) was issued to and discussed with Joseph E. Blake, Director of Regulatory Affairs. A copy of the FDA-483 is attached for your information. The inspection noted the following CGMP deviations:

- failure to establish written procedures for the responsibilities of the Quality Control Unit [Title 21 Code of Federal Regulations (21 CFR) Part 211.22];
- failure to maintain Master Production Records [21 CFR Part 211.186];
- failure to establish written procedures for and to perform end product testing to assure each batch conforms to the purity, identity, and strength to which it purports [21 CFR Part 211.165];
- failure to establish written procedures and perform testing on incoming components, drug containers, and label examination [21 CFR Part 211.110];
- failure to establish written procedures and perform stability testing of drug products to determine storage conditions and expiration dates [21 CFR Part 211.166];
- failure to establish written procedures for the review and maintenance of batch records [21 CFR Part 211.188];

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- failure to establish written procedures for handling complaints [21 CFR Part 211.198];
- failure to establish written procedures for the cleaning and maintenance of equipment [21 CFR Part 211.67];
- failure to establish written procedures for the storage, handling, and issuance of labeling [21 CFR Part 211.130]; and
- failure to document that personnel employed in drug manufacturing operations are trained on a continuing basis and with sufficient frequency to assure they remain familiar with CGMP requirements applicable to their assigned function [21 CFR Part 211.25(a)].

FDA analysis of Martin's Brand PET WORMER for Dogs and Cats of All Ages 8 fl. oz., lot #135, found 3.02 or 71.1% of the labeled amount (on original analysis) and 3.89 or 91.6% of the labeled amount (on check analysis) of 4.25 grams piperazine base /100 cc. A drug is adulterated pursuant to Section 501(c) of the Act if its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Additionally, the following Martin's Brand veterinary drugs are misbranded pursuant to Section 502(b)(1) of the Act. PET WORMER, D-WORM, SCARLET OIL SMEAR For Horses, VIOLET WOUND DRESSING, HORSE ANTISEPTIC OINTMENT, AMINE- IODIDE, and PINE TAR OIL are misbranded because the labeling of the drugs bears the incorrect address of your manufacturing facility.

This is not an all-inclusive list of deviations documented during the inspections. As a manufacturer of animal drugs, it is your responsibility to assure compliance with the Act and all applicable regulations. You should take prompt action to correct the deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. Possible actions include 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 or will take to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the Food and Drug Administration, Dallas District Office, Attention: Brenda C. Baumert, Compliance Officer, at the above letterhead address.

Sincerely,



Michael A. Chappell
District Director