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Certified/Return Receipt Requested

September 9, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Louis G. Van Daele, President
Diamond Animal Health, Inc.
2538 Southeast 43rd Street
Des Moines, IA 50317

Ref. # - KAN-97-025

Dear Mr. Van Daele:

During an inspection of your veterinary drug manufacturing facility located at Des Moines, Iowa, conducted on August 5 to 14, 1997, our investigator found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals regulations (21 CFR, Part 211). Such deviations cause veterinary drugs being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Our investigation found failure establish and use a written procedure for the handling of complaints involving your drug products; failure to adequately control the environment of your Class 100 aseptic filling room in that there is no unidirectional flow of air and employees are gowning improperly prior to entering the room; conducting inadequate environmental monitoring in that employees who met or exceeded the CFU per person level were still allowed to work in the aseptic room and manufacture sterile products, no documented investigations of instances where total airborne particulates exceeded the action limits, and no monitoring during set-up of filling equipment.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with you. This form is a comprehensive listing of the investigators' observations of deviations found during the inspection.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

cc: Fred M. Schwarzer, CEO
Heska Corporation
1825 Sharp Pointe Drive
Fort Collins, CO 80525

Copy: Related Individual

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