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PURGED *RJK*

June 30, 2000

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100**WARNING LETTER**xc. HFI-35
DWA**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 41

Guy Pochard
President
A & L Laboratories
1001 Glenwood Avenue
Minneapolis, Minnesota 55405

Dear Mr. Pochard:

During an inspection of your veterinary drug manufacturing facility located at Minneapolis, Minnesota, conducted on June 1 and 5, 2000, our investigators found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals [Title 21, Code of Federal Regulations Part 211 (21 CFR 211)]. Such deviations cause veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found the following deviations:

1. 21 CFR 211.84(d) Samples shall be examined and tested as follows: (1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used. (2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Although you are not required to use components that meet USP/NF specifications, you must have written specifications for all components. The USP/NF happens to be a convenient source. You must run at least one *specific* identification test on each component *before* release for use in

Guy Pochard
June 30, 2000

manufacturing. If you rely on a supplier's certificate of analysis, you must validate the supplier's test results at appropriate intervals.

No certificate of analysis was available for [redacted] since March 2000 although biweekly shipments are received. During this time nothing was done to determine the identity, strength, or quality of the product.

2. 21 CFR 211.25(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions.

Many of your employees have never received CGMP training.

3. 21 CFR 211.100(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

You have not validated the processes used to manufacture all drug products.

4. 21 CFR 211.80(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug products containers and closures; such written procedures shall be followed.

You are not following your written procedures for water quality, release of components, and storage of FDA regulated and non-FDA regulated products.

It does not appear that you have validated the software used for [redacted] analysis. Our investigator submitted an example of your calculations for a formulation containing [redacted]. The lot number is [redacted] and the analysis is dated 5/31/00 (copy enclosed). How does your software calculate the values for the [redacted], and [redacted]? Using the procedures as described in [redacted] the following values were obtained.

[redacted]
[redacted]
[redacted]

[redacted]
[redacted]
[redacted]

Page Three

Guy Pochard
June 30, 2000

In addition, you can improve the accuracy of the calculation by including a  that will yield an  of approximately  and making this the midpoint of the standard curve. If these suggestions are followed, the instrumental errors will be reduced to a minimum.

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.

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 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. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address on the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

Enclosure

xc: Phillipe Vignon
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