

**WARNING LETTER**

September 8, 2000

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ref. KAN 2000-027

Marvin G. Moose, Ph.D.  
Chairman/Owner  
Ameri-Pac, Inc.  
1515 South 2<sup>nd</sup> Street  
Leavenworth, KS 66048

Dear Dr. Moose:

During an inspection of your veterinary drug manufacturing facility conducted on August 8-15, 2000 our investigator 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 a variety of deviations including the following:

1. Process validation has not been performed by your firm for Hydrogen Peroxide 3%, Kaolin-Pectin or Bismusal.
2. No annual product review conducted by appropriate personnel has been performed since 1998.
3. Production steps you perform on Kaolin-Pectin and Bismusal are not included in the Master Production Record or the individual batch records.
4. Adequate monitoring and microbial testing are not performed on your water system.
5. You do not have written procedures identifying the person or persons who have quality control authority concerning the acceptance or refusal of product.

The above list is not intended to be an all-inclusive list of Good Manufacturing Practice (GMP) deviations. As a manufacturer of veterinary pharmaceuticals it is your responsibility to assure your operations and the products you manufacture and distribute are in compliance with the law.

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Dr. Marvin G. Moose  
September 8, 2000

At the close of the inspection a list of Inspectional Observations, Form FDA483 was issued to and discussed with Mr. Steven C. Stumpf, Vice President of Manufacturing. A copy of the Form FDA483 is enclosed for your information.

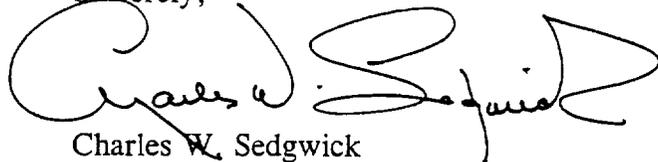
You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory actions without further notice including but not limited to seizure and/or injunction.

We acknowledge the receipt of the response signed by Mr. Stumpf, dated August 29, 2000, submitted by your firm in response to the Form FDA483. We request you provide documentation of the corrections that were pending at the time of your response letter (for example, the quality control SOP).

In addition, you indicate you have hired consultants to assist you in achieving and maintaining GMP compliance. Please provide the name and qualifications of the consultants you have contracted with so we can make that part of your official file.

Please provide the requested information and any further response you want to submit within fifteen (15) working days. Your reply should be directed to Ralph J. Gray, Compliance Officer at the above address.

Sincerely,



Charles W. Sedgwick  
District Director  
Kansas City District

Enclosure: Form FDA483

cc: Steven C. Stumpf  
Vice-President of Manufacturing  
Ameri-Pac, Inc.  
1515 South 2<sup>nd</sup> Street  
Leavenworth, KS. 66048