



DEPARTMENT OF HEALTH AND HUMAN SERVICE

91143d
Public Health Service

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905
Telephone: (913) 752-2100

April 16, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2001-018

Everett B. Hughes, President & CEO
Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215

Dear Mr. Hughes:

On January 16 - February 6, 2001 Food and Drug Administration (FDA) investigators performed an inspection of your veterinary drug manufacturing operation at 12340 Santa Fe Trail Drive, Lenexa, Kansas. This inspection revealed serious deviations from the current Good Manufacturing Practices for the manufacture or finished pharmaceuticals as detailed in Title 21 Code of Federal Regulations, Parts 210 and 211. These deviations cause your animal drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the methods used in or the facilities or controls used for their manufacture, processing, packing or holding do not conform to current good manufacturing practices.

Deviations documented include but are not limited to:

1. Failure to establish and/or follow adequate procedures to control microbiological contamination in products purporting to be sterile. [21 CFR 211.113(a)(b)] Examples include:
 - Inadequate sterilization of equipment used in aseptic processing
 - Inadequate monitoring of all clean room locations and of personnel involved in aseptic processing operations
 - Inadequate positioning of personnel involved in aseptic processing in that one or more individuals are fully or partially within the curtained areas of the Class 100 room during an entire fill run
 - Inadequate gowning was observed on a number of occasions during the inspection
 - Inadequate validation of aseptic processing operations in that media fills were deficient

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2. Failure to perform adequate investigations on lots of aseptically filled products that were out of established sterility specifications during initial testing. [21 CFR 211.192]
3. Failure to establish adequate procedures detailing out-of-specification investigations with reference to laboratory procedures. Specifically your procedures do not require documentation of laboratory investigations, allows multiple testing when initial investigations are inconclusive and does not adequately identify or define the parameters for multiple failures. [21 CFR 211.192]
4. Failure to have adequate complaint procedures established in that instructions concerning FDA post-marketing adverse drug experiences do not describe what needs to be reported or establish timeframes for reporting. [21 CFR 211.198(a)]

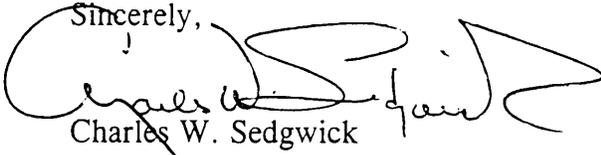
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and current regulations.

The Food and Drug Administration has reviewed your firm's response dated February 20, 2001 which is a response to the observations listed on the Form FDA 483. Your letter was taken into consideration during the preparation of this correspondence. We shall be issuing a detailed response to your February 20, 2001 letter.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or injunction. Also other Federal agencies are informed about the Warning Letters issued so they may consider this information when awarding government contracts.

Please inform this office, in writing, within fifteen (15) working days of receipt of this letter of the steps you are taking, in addition to those detailed in your February 20, 2001 letter, to correct these deviations. If you desire to have the original response stand as your response to this letter please inform us in writing. If the timeframes you stated for the completion of the corrections to the various deficiencies documented please inform us at the time of your response.

You should direct your reply to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District