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6/30/97
EJG

WARNING LETTER

MAY 27 1997

97-DT-09

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ronald J. Vallancourt, D.V.M.
Vice President, Regulatory Affairs and Responsible Head
Immuno-U.S., Inc.
1200 Parkdale Road
Rochester, MI 48307-1744

Dear Dr. Vallancourt:

During an inspection of your facility between March 18 and April 1, 1997, violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 211 and 600 were documented as follows:

1. Failure to follow or maintain 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 [21 CFR 211.100 - 211.115]. For example:
 - a. There has been no process validation completed for the manufacturing of 5% and 25% Albumin.
 - b. Albumin vial stoppers are not validated for removal of pyrogenic properties.
 - c. Validation of the [REDACTED] Steam sterilizer was not complete.
 - d. The [REDACTED] stopper/washer used to wash the Albumin vial stoppers is not validated for removal of residual detergent.
 - e. There are no written procedures on the media fill used on the filling line for Albumin.
 - f. There are no written procedures for the rework of the Albumin product.

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Regulatory Affairs and Responsible Head
Immuno-U.S. Inc., Rochester, MI 48307-1744

- g. There are no written procedures regarding what testing will be conducted by an outside contractor to assure the integrity of their HEPA filters. In addition there is no documentation that the test results are reviewed and approved by Immuno.
 - h. An evaluation has not been performed to determine that disinfectants do not inhibit the nutritive properties of media used for environmental monitoring.
 - i. An evaluation has not been performed to determine that solutions used in the aseptic core and sanitizing agents used for small equipment in production areas are effective.
2. Failure to establish Laboratory controls (21 CFR 211.160) regarding the storage of the Biological Indicators used for autoclave sterilization as required by the manufacturer.

We acknowledge receipt of your April 17, 1997, written response which addresses the inspectional observations on the FDA Form-483 issued at the close of the inspection. Corrective actions addressed in your letter may be referenced in your response to this letter, as appropriate, however, your response did not provide sufficient detail to fully assess the adequacy of the corrective actions. Our evaluation of your response follows, and is numbered to correspond to items listed on the Form FD-483:

- 1. Please submit the validation data and evaluation for equipment and processes listed in your bullet number four - i.e. plasma thawing- sterilization procedures, sterile filling procedures, etc. We understood that you did not have a validation protocol for Albumin 5% and 25%. If you have established the validation criteria, generated/analyzed the data, evaluated the process - please submit the documentation and identify the statistical tool utilized.

Your responses for items 2-15 appear to be adequate and will be verified during our next inspection.

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16. We understand that the Water for Injection and media fills were discarded in February after a failure. Please note that the area should have been monitored in accordance with your Standard Operating Procedure.

Neither this letter nor the list of inspectional observations is meant to be an all inclusive list of deviations. It is our responsibility to ensure that your facility is in compliance with the provisions of the Federal Food, Drug and Cosmetic Act and all applicable regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction, license suspension and/or revocation.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken or will take to correct or prevent these deviations. 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 following address:
Ms. Judith A. Putz, U.S. Food and Drug Administration,
1560 East Jefferson Avenue, Detroit, Michigan 48207-3179.

Sincerely,



Brenda J. Holman
District Director
Detroit District

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