

April 28, 1998

CERTIFIED - RETURN RECEIPT REQUESTED

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

Robert Myers, D.V.M.
Director
Michigan Biologic Products Institute
3500 North Martin Luther King, Jr., Blvd.
P.O. Box 30035
Lansing, Michigan 48909

Dear Dr. Myers:

The Food and Drug Administration (FDA) has performed a preliminary review of Michigan Biologic Products Institute's (MBPI) letter dated March 20, 1998, which was submitted in response to the list of inspectional observations (Form FDA 483) issued on February 20, 1998. Our review focused on the eleven lots of anthrax vaccine that were voluntarily quarantined by MBPI as a result of your telephone conversation with the FDA on or about February 27, 1998. During that conversation, the FDA raised concerns about inspectional issues related to potency testing, sterility testing, and the presence of particulates in a number of lots of anthrax vaccine.

With regard to the 7 lots of anthrax vaccine quarantined because of concerns about potency testing, we acknowledge receipt of your PLA supplement (reference number 91-0079) dated March 16, 1998. While we recognize that extensive discussions between MBPI and the appropriate FDA review offices regarding the criteria for potency testing is an integral component of this supplement, it is requested that you provide the agency with lot specific potency testing protocols and testing results (raw data) so that we may continue our assessment of the suitability of these lots.

With regard to lot FAV016 of anthrax vaccine, which had 6579 vials rejected due to particulates identified as "inert gasket material", please submit a detailed record of your investigation, including your evaluation of the vials remaining in inventory. Additionally, please describe in detail the "additional analysis of the lot for added assurance," referenced on page 15 of your submission.

With regard to lots, FAV029, FAV032, and FAV035, of anthrax vaccine quarantined due to concerns related to sterility testing, please submit a detailed record of your investigation(s), sterility testing protocols and the results of all additional analyses performed.

In addition to providing the agency with the above requested information, please verify in writing that these eleven lots are, and will remain, in quarantine until further notification from the agency.

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As previously emphasized in FDA's letter dated April 7, 1998, the FDA recognizes the important role played by MBPI in meeting the special public health needs for anthrax vaccine. It is, therefore, critically important that MBPI meet the requirements and applicable standards in your licenses for the manufacture of this product. If you have questions regarding this letter, please do not hesitate to contact me or Mark Elengold, Deputy Director, Center for Biologics Evaluation and Research at (301) 827-0372.

The agency's final assessment of your response to the list of inspectional observations (Form FDA 483) will be provided under separate cover in the near future.

Sincerely,



Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation and Research

cc: Mr. Anthony M. Luttrell
Director, Quality Assurance/Quality Control
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