



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Nashville District Office

297 Plus Park Boulevard  
Nashville, TN 37217

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8/28/97  
JEA

August 27, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. William Propst, President  
Vintage Pharmaceuticals, Inc.  
120 Vintage Drive  
Huntsville, AL 35811

WARNING LETTER - 97-NSV-15

Dear Mr. Propst:

During an inspection of your manufacturing facility on July 21 - August 1, 1997 our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Our inspection revealed the release of products for distribution without stability data to support the two year expiration date on the label, failure to validate the Laboratory Information System used in the chemistry laboratory and stability samples for accelerated stability studies not being assayed in a timely manner. The inspection also revealed the formulation of products with a 5% to 25% excess active ingredient with release specifications allowing 90% to 135% of declared active ingredient. Other deviations included formula changes from batch to batch during working of the batches without validating the manufacturing processes and reworking procedures as well as the analytical methods used by your laboratory.

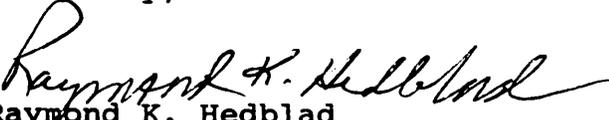
The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Until violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

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These deviations from Current Good Manufacturing Practice are a very serious concern to the Food and Drug Administration. We are therefore scheduling a meeting for September 18, 1997 at 1:00 p.m. at 297 Plus Park Boulevard, Nashville, Tennessee. We are requesting that you attend the meeting to discuss your drug manufacturing operation and the steps you have taken to correct the violations noted during the inspection. We will also discuss any written response you may want to present at the meeting.

Please respond if you can attend this meeting to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217, telephone (615)781-5389, Ext. 125 by September 11, 1997.

Sincerely,

  
Raymond K. Hedblad  
Director, Nashville District

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