FDA Warning Letter

From,
Jagat Singh,
19009 New Avenue
Sliver Colony
Delhi

Date: 21st Aug. 2020

To,
Mr. Rajiv Bhatia
Director
XYZ Laboratories Limited
Delhi, India

Subject: Warning Letter

Dear Mr. Bhatia,

The Food and Drug Administration (FDA) inspected your drug manufacturing XYZ Laboratories Limited located at Silver Colony, Delhi.

During the investigation, our inspector noticed some deviations. They are:

Failure to ensure all the production deviations are evaluated and the following conclusions are made:

Your company has failed to follow the written procedures. Your response to our procedures is inadequate. You also did not review all the production records. Conduct a risk analysis to predict the quality effects of any such identified failures.

Failure of your unit to adequately perform some annual product reviews:

We also reviewed your annual product reviews and observed a lot of deficiencies. Your response to this inspection was also inadequate. You did not explain how your resource planning will help you to prevent errors in the future.

In your response to this letter we want you to conduct a review of all APR for the past three years. You also need to provide a tabular summary of your review.

Sincerely,

Jagat Singh, PhD
Compliance Officer