

FDA 483 Warning Letter

Food and Drug Administration

Division of Pharmaceutical Quality Operations

Central Region

Date: May 31, 2024

ABC Manufacturing Corp

789 Health Avenue

Wellness City, OH 44106

Subject: FDA 483 Warning Letter for Observational Findings

Dear ABC Manufacturing Corp,

1. Introduction

Following our inspection of your facility from April 20-25, 2024, the FDA has issued this FDA 483 Warning Letter to address the observational findings of non-compliance with regulatory standards.

2. Observational Findings

Our inspection identified several critical deficiencies, including:

- Inadequate cleaning and sanitization procedures in production areas.
- Incomplete batch production records.

- Insufficient validation of analytical methods.

3. Impact of the Findings

The deficiencies noted compromise the integrity and safety of your pharmaceutical products. These findings are indicative of systemic issues that must be addressed to ensure compliance and protect public health.

4. Required Actions and Consequences

You are required to respond to this letter within 15 business days, detailing your corrective actions and preventive measures. Non-compliance may lead to enforcement actions such as recalls, fines, and legal penalties.

5. Support and Resources

We recommend consulting with a regulatory compliance expert to address the identified issues. The FDA offers resources and guidance documents to assist in achieving compliance.

6. Conclusion

We expect prompt and effective action to resolve these deficiencies. Ensuring compliance with FDA regulations is crucial for the continued operation of your manufacturing facility.

Sincerely,

Dr. Robert Lee

Regional Director

Division of Pharmaceutical Quality Operations

Food and Drug Administration