**FDA 483 Warning Letter**

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**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**