[Company Name]

[Your address]

[Your City, State ZIP Code]

[Date]

[District Director name]

District Director

[Name of District Office] District Office

U.S Food and Drug Administration

[District address]

[City, State ZIP Code]

**Subject:** Response to [FDA 483 Observations / issued to on [Date of Inspection] .

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Dear [District Director ,

On [Date] , U.S Food and Drug Administration (FDA) Investigators [Name of FDA , concluded their inspection of [Company Name] (FEI number: [FEI Number] - hereafter referred to as [Short Company Name] ) located in [City, State] . Following this inspection, we received the inspection observations documented on Form 483.

This letter serves as our initial response to the observations noted in the Form 483. We acknowledge the importance of these findings and are committed to addressing them thoroughly. We will provide a comprehensive supplemental update to the FDA on or before [Month Day, Year] , followed by [e.g. monthly] updates to keep you infor-med of our progress.

We take the observations seriously and are dedicated to implementing all necessary corrective actions to ensure that our systems comply with FDA regulations and that our products remain safe and effective. In addition to addressing the specific items listed in Form 483, we are actively working to identify and resolve any systemic issues that may have contributed to these observations.

If you have any questions or need any clarification, please do not hesitate to contact me at [Name of the Company Contact]

Sincerely,

[Name of the Company Contact]

[Title]

[Company Name]

**Response to FDA 483 observations**

This section [Short Company Name] lists [Form 483/Warning letter] observations, including actions that have been taken immediately, and planned actions.

> Note: Copy each observation from Form 483 verbatim, including any annotation. Give detailed responses to each observation. Report your approach to addressing the observations and outline any overarching corrective actions or quality system improvements.
>
> Note: Copy each observation from Form 483 verbatim, including any annotation.

**FDA Observation No 1 -** [Title of Observation]

*Copy observation No. 1 from Form 483/Warning Letter verbatim, including any annotation.*

**Response:**
Include a detailed response to the observation. Restate the issue clearly to demonstrate understanding. Provide a clear explanation and evidence to support your position.

**Root cause analysis:**
Indicate the root cause of the issue. Include any analysis conducted to understand underlying issues that may have contributed to the observation. If the root cause analysis has not been completed, indicate your commitment to continue the investigation.

**Corrective actions Obs. No 1:**
Explain how the company plans to fix the issue.

**Immediate actions taken**: Provide a list and explanation of the immediate corrective actions completed. Provide dates for completed actions and make reference to the evidence in the attachments.

**Planned actions:** Outline steps your company is taking to address the issue systematically. Include a timeline for completing planned actions. Preventive actions: List and explain the long-term actions to prevent recurrence. Include a timeline for completing planned actions.

FDA Observation No [X]: FDA Observation
Corrective actions Obs. No [X]: Corrective actions Obs

Note: Describe the methods for verifying the effectiveness of all actions.

## Final discussions

After addressing individual observations, describe any broader changes to your quality management system and explain how these changes will prevent similar issues in the future. Conclude the main body by reaffirming your commitment to quality and compliance, providing a timeline for future updates to the FDA, thanking them for their feedback, and offering to provide any additional information they may require.

## Attachments

Include relevant supporting documents that provide evidence of your corrective actions and commitment to improvement (e.g.updated Standard Operating Procedures (SOPs), training records, CAPA plans, progress reports, revised forms or templates, audit reports, test results or data, and photographs of physical changes or improvements.
Label each piece of evidence clearly, one with a number or letter, and reference them in the main body where appropriate.
Provide a table of contents for the attachments and ensure all are legible and in English (or translated if necessary).