[[DATE]]

[District Director Name]

District Director

[NAME] District Office

U.S. Food and Drug Administration

District Address

City, State Zip

Re: [Firm Name]

Initial Response to the

[DATE] Inspectional Observations (FDA-483)

Dear [DD NAME],

On [DATE], U.S. Food and Drug Administration (FDA) Investigators concluded an inspection of the [Company] (hereafter referred to as “[Short Name]” or the “company”) facility located in [City, State] and issued Inspectional Observations on the form FDA-483. We provide our initial response below. We plan to submit our next update report to FDA on or before [Month Day, Year], followed by monthly updates until quarterly updates become more appropriate.

We recognize and take seriously the significance of the observations in the FDA-483, and are committed to taking all actions necessary to ensure that our systems are in compliance with FDA requirements, and that our products are safe and effective. As is described in our detailed response below, in addition to correcting the specific items listed in the FDA-483, we have taken and are continuing to take actions to address systemic issues.

In Appendix 1, “Response to the FDA-483 dated [DATE],” we describe our completed and planned actions. To facilitate review, the FDA-483 observations are italicized, followed by our response in regular font. Supporting documents relating to actions we have already taken are listed in Appendix 2 “List of Attachments.” Appendix 3, “Table of Actions,” is a comprehensive list of the completed and planned actions relating to each FDA-483 Observation.

Next we highlight some of the activities underway to demonstrate our commitment to driving improvements, not only to the specific areas found in the inspection, but to the business as a whole. The following are just a few examples:

1. [Example 1]
2. [Example 2]

We consider the information contained in this letter and its attachments to be confidential commercial information and not subject to disclosure under the Freedom of Information Act. Accordingly, we have designated this letter and its attachments as confidential.

[I would welcome the opportunity to meet with you to discuss the progress made to date and the planned actions outlined in the attached response.] [I welcome the opportunity to discuss the progress made to date and the planned actions outlined in the attached response.] In the meantime, should you have any questions, please contact me at the telephone number: [Company Contact Phone].

Respectfully,

[company Contact]

[Title]

[Company Name]

[City, State]

Appendices

1. Response to FDA-483

2. List of Attachments

3. Table of Actions

In this section, [COMPANY] lists the Warning Letter items and the text of the FDA-483 Observations in italic font type, and the actions completed and planned follow in regular font. Appendix 2, “List of Attachments,” contains the supporting documents related to the completed and planned actions outlined in our responses.

**FDA Observation 1**

*Copy observation verbatim, including annotation, if any.*

|  |  |
| --- | --- |
| Response: |  |
| Completed Actions: | On [Month day, Year, Company [State Completed Action]]. See Appendix 2, Attachment XX for a copy of the [Describe Records] records.  On [Month Day, Year, Company [State Completed Action]]. See Appendix 2, Attachment XX for a copy of the [DESCRIBE RECORDS] records. |
| Planned Actions: | By [Month Day, Year, Company] will [Describe Planned Actions].  By [Month Day, Year, Company] will [Describe Planned Actions].  [company] also plans to complete [DESCRIBE RECORDS] by [Month day, Year].  [company] considers this item to be closed. |

**FDA Observation 2**

*Copy observation verbatim, including annotation, if any.*

|  |  |
| --- | --- |
| Response: |  |
| Completed Actions: |  |
| Planned Actions: |  |

|  |  |  |
| --- | --- | --- |
| **Appendix 2 - List of Attachments** | | |
| **Attachment** | **Title/Description** | **Number of pages** |
| 1. |  |  |
| 2. |  |  |
| 3 |  |  |

| **Appendix 3** | **Table of Actions** | |
| --- | --- | --- |
| **[date] -FDA-483** | **ACTIONS** | |
| **Completed Actions** | **Planned Actions** |
| ***FDA-483 Observation 1*** |  |  |
| ***FDA-483 Observation 2*** |  |  |
| ***FDA-483 Observation 3*** |  |  |
| ***FDA-483 Observation 4*** |  |  |
| ***FDA-483 Observation 5*** |  |  |
| ***FDA-483 Observation 6*** |  |  |
| ***FDA-483 Observation 7*** |  |  |
| ***FDA-483 Observation 8*** |  |  |
| ***FDA-483 Observation 9*** |  |  |
| ***FDA-483 Observation 10*** |  |  |
| ***EXAMPLE TEXT*** | Provided the procedure entitled, “Title”, \*\*\*.  Completed the complaint investigation, \*\*\*. | We consider this item to be closed. |