U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via UPS
Return Receipt Requested

[DATE]
[TITLE & FULL NAME]
[POSITION]
[COMPANY NAME]
[MAILING ADDRESS]

Dear [TITLE & LAST NAME]:

The U.S. Food and Drug Administration (FDA) conducted an inspection at [FACILITY NAME], FEI [NUMBER], located at [FACILITY ADDRESS], from [DATE] to [DATE]. FDA has determined that the inspection classification of this facility is "official action indicated" ("OAI").[1]

Based on this inspection, this facility is considered to be in an unacceptable state of compliance with regards to current good manufacturing practice (CGMP). This facility may be subject to a CGMP regulatory or enforcement action based on this inspection, and FDA may withhold approval of any pending applications or supplements in which this facility is listed.

If you have any questions regarding this letter, you may contact CDER-OC-OMQ-Communications@fda.hhs.gov.

Sincerely,

/signature/

[DD or Designated Authority]
[TITLE]
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

Enclosure: Form FDA 483

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.