Custom Compounding Centers, LLC
Inspection and 483 Response
FEI 3009855773

Mr. Alonza Cruse

District Director

U.S. Food and Drug Administration

19701 Fairchild

Los Angeles, CA 92612-2506

Re: Custom Compounding Centers, LLC
Inspection and 483 Response
FEI 3009855773

Dear Mr. Cruse,

This submission will provide an update to Custom Compounding Centers, LLC's ("CCC" or "we") 09-18-2014 response to FDA Los Angeles District ("District") issued 483 Form dated 08-28-2014, update dated 10-09-2014.

Custom Compounding Centers, LLC

10/17/2014

On behalf of Custom Compounding Centers, LLC ("CCC"), I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information in the attached letter responding to the FDA's Form 483 observations for Custom Compounding Centers, LLC issued 08/28/2014, excluding attachments/exhibits, on the FDA's website.

It has been our pleasure to work with the district in the interest of patient safety as we make additional modifications to our system. We believe that we have been diligent in our response to the issued Form 483 dated 08-28-2014. If the responses contained herein are not considered adequate to meet the requirements necessary for our stated position under section 503(a) of the Federal Food Drug and Cosmetic Act, and then please let us know at your earliest opportunity. It is our intention, with the assistance of the District, to comply fully with USP 797 Guidelines and all applicable state and federal laws regulations and guidelines

Schedule for Updates and Conclusion:

As stated, updates informing the District of progress on our planned activities on **October 10 (previous submission)** and October 20, 2014 **(please see this 10/17/2014 submission)**. We anticipate that all commitments to planned activities will be complete. If the District would like any additional information before those dates, please let us know.

Again, we appreciate the observations that the District provided regarding our compounding pharmacy and hope it agrees that with the proposed steps we are taking and that Custom Compounding Centers, LLC should be allowed to continue to provide high-quality compounded prescription drugs to the patients and practitioners who rely on them.

Continued Response to Observation 1, item b):

As previously stated, we believe that CCC is in compliance with USP 797: Viable and Nonviable Environmental Sampling (ES) Testing, "Environmental Particle Testing Program" – Engineering Control Performance Verification that states "Certification procedures such as those outlined Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed." And Total Particle Count (same reference) Certification is within established guidelines shall be performed no less than every 6 months ....." **(PLEASE SEE EXHIBIT B-1 CLEAN ROOM CERTIFICATION – previous submission** - Clean Room Certification Report dated April 25, 2014) performed by consultant Controlled Environmental Testing Services.

Additional Action by CCC:

CCC has added non-viable particulate monitoring equipment to enable active monitoring of non-viable air particulates during aseptic procession of compounded patient prescriptions in the ISO 7 and ISO 5 environments. This additional equipment will provide active monitoring of the aseptic processing area for non-viable particulate matter during aseptic processing. Proper operation and training will be conducted with affected employees and will be documented. (See exhibit _A_ Lighthouse model 3016 Particle Counter or equivalent picture) New equipment operation and training has been conducted with all compounding staff to ensure that proper procedures are followed and logged as specified. (See exhibit _B_ copy of

personnel training log, see Exhibit _**C**_ copy of the Particle Count Sampling Policy and Procedure (ASEP 132), see exhibit _**D**_ copy of particulate monitoring log, and see exhibit _**E**_ copy of particulate measurement point's diagram.

If you have any questions or issues regarding this updated response or associated matters, please contact Custom Compounding Centers, LLC – Paul Wheeler, Pharmacist in Charge at (714) 894-2120

Sincerely,

Paul R. Wheeler, Pharm.D.
President and Pharmacist in Charge
Custom Compounding Centers, LLC

/Exhibits

Cc: Ms. Jessica Mu, FDA, Los Angeles District