

**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.

Paul R. Wheeler

10/9/2014

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.

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OCT 10 2014

LOS ANGELES
DISTRICT
DIRECTOR OFFICE

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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, we intend to submit updates informing the District of progress on our planned activities on **October 10 (please see this 10/09/2014 submission)** and October 20, 2014. By that time 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.

UPDATE TO RESPONSE TO OBSERVATION 1, ITEM B):

In addition to "Certification performed by a qualified individual no less that every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed..." (USP 797 Engineering Control Performance Verification) Custom Compounding Centers has added a continuous magnehelic pressure monitoring station. Continuous pressure differentials from cleanroom to anteroom and from anteroom to ambient area is now monitored and logged twice per shift.

(See exhibit **_A_** (pic of gauges). New Equipment operation and training has been conducted with all compounding staff to ensure that proper procedures are followed and pressures logged as specified. (See exhibit **_B_** copy of personnel training log, See Exhibit **_C_** copy of Policy and Procedure ASEP 129 Revision and See exhibit **_D_** copies of pressure differential logs).

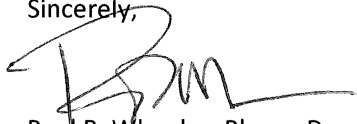
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UPDATE TO RESPONSE TO OBSERVATION 3:

In addition to the information provided in the original response dated 09-18-2014 regarding potency testing for individual patient prescriptions, Custom Compounding Centers has installed printer capacity for all balances used to weigh active ingredients. This process will provide weight verification for all active ingredients used in the compounding process. (See exhibit E (picture of printer attached to balance, See exhibit F copy of training record of staff, See exhibit G copy of Policy and Procedure ASEP 124A Revised).

If you have any questions or 4 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