DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900

December 14, 2015

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834

Dear Ms. Herold,

The purpose of this letter is to refer to the California State Board of Pharmacy (BOP) for appropriate follow-up, a pharmacy licensed by the California BOP, Custom Compounding Centers, LLC, 10525 Humbolt Street, Los Alamitos, CA 90720 (Licensed Sterile Compounding License #99648 and Retail Pharmacy License #50368).

FDA issued a warning letter to the firm on May 15, 2013, and reinspected the firm from August 4, 2014, to August 28, 2014. The FDA investigator was accompanied by a California state investigator on the first day of the inspection. Based on the firm's response to the warning letter and the results of FDA's reinspection, it appears that the firm addressed the violations contained in the warning letter. However, during the August 2014 reinspection, FDA investigators did observe some deviations from appropriate sterile practice that still need to be corrected to prevent product contamination that could put patients at risk.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Custom Compounding Centers, LLC, and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and dispenses. In a letter to FDA dated August 7, 2014, the firm advised FDA that it "is only providing compounded sterile products pursuant to a patient prescription at this time" and "does not provide any products for office use."

A redacted copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM417936.pdf.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection, and will send the firm a letter documenting that the Warning Letter matter is closed. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, and FDA believes that the corrective

actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the California State BOP for follow-up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Jessica Mu, Compliance Officer, at (949) 608-4477.

Sincerely,

LCDR Steven Porter, Acting Director
Los Angeles District