



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Pacific Region
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612

June 23, 2015

Stanley C. Weisser, R.Ph., President
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Dear Mr. Weisser:

The purpose of this letter is to refer to the California State Board of Pharmacy (BOP) for appropriate follow-up the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the California BOP, South Coast Specialty Compounding dba Park Compounding (Park Compounding), located at 9257 Research Drive, Irvine, CA 92618 (California Sterile Compounding License #99026).

FDA inspected the firm from June 23, 2014, to July 2, 2014. The California BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at:

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM414754.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Park Compounding 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 the firm's response to the Form FDA 483, received by FDA on July 16, 2014, the firm advised FDA that it prepares "both sterile and non-sterile preparations solely on the prescription order of a licensed practitioner."

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm's program to ensure that each process used is able to produce sterile product without contamination, and to evaluate the competency of all personnel who engage in these operations, is inadequate. For example, personnel do not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations.

2. The firm failed to verify that the methods used to perform sterility testing on finished injectable products were adequate. For example, the firm did not direct its contract testing laboratory to perform suitability testing for the sterility test method to demonstrate that the firm's products do not interfere with the test.

Park Compounding committed to FDA in its response to the Form FDA 483, received July 16, 2014, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctible.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. 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, or by email at jessica.mu@fda.hhs.gov.

Sincerely,

A handwritten signature in blue ink that reads "Alonza Cruse for". The signature is stylized and cursive.

Alonza Cruse, Director
U.S. Food and Drug Administration
Los Angeles District Office