June 3, 2018

C. Erica White, Executive Director
Florida Board of Pharmacy
4052 Bald Cypress Way, Bin #C04
Tallahassee, Florida 32399-3254

Dear Ms. White:

The purpose of this letter is to refer to the Florida State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor practices observed during an FDA inspection at a pharmacy licensed by the Florida BOP, Pharmacy Specialists of Central Florida, Inc., dba Pharmacy Specialists (Pharmacy Specialists), located at 393 Maitland Avenue, Altamonte Springs, FL 32701 (Pharmacy license # PH15908).

FDA inspected the firm from June 5, 2017, to June 8, 2017. Florida State BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observation from the inspection can be found at 483 with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Pharmacy Specialists 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 distributes.

During the inspection, the FDA investigator observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm produced hazardous drug products without providing adequate containment, segregation, and cleaning of work surfaces and utensils to prevent cross-contamination.

Pharmacy Specialists committed to FDA in its response to the Form FDA 483, dated June 15, 2017, to correct the deviations in the Form FDA 483 and provided

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division 2
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documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Florida 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 me at (214) 253-5288.

Sincerely,

John W. Diehl -S

Digitally signed by John W. Diehl -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S, 0.9.2342.19200300.100.1.1=2000099727
Date: 2018.06.03 10:21:39 -05'00'

LCDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Cc: Samuel D Pratt, President
Pharmacy Specialists of Central Florida, Inc. Dba Pharmacy Specialists
393 Maitland Avenue
Altamonte Springs, FL 32701