



VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

January 23, 2017

Erica White Executive Director
Florida Department of Health
Board of Pharmacy
4052 Bald Cypress Way Bin C-04
Tallahassee, FL 32399-3258

Dear Ms. White:

The purpose of this letter is to notify the Florida State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration does not intend to take further action with regard to an inspection of a pharmacy licensed by the Florida BOP, HHCS Pharmacy, Inc. dba Freedom Pharmacy, located at 3901 E. Colonial Drive, Orlando, FL 32803 (License #: PH 9019).

FDA inspected the firm from October 11, 2016 to October 14, 2016, as a follow up to a warning letter that was issued to the firm on May 14, 2015. A copy of the warning letter can be found at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm448689.htm>. The Florida BOP was informed of the inspection but did not accompany FDA investigators during the inspection. No Form FDA 483 was issued to the firm following the October 2016 inspection.

During the October 2016 inspection, the FDA investigators learned that the firm had relinquished its Florida BOP Sterile Compounding Permit. In addition, our investigators reviewed a small sample of records for products compounded by Freedom Pharmacy 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. After review of the firm's records, FDA does not intend to take further action with regard to the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. 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 Andrea Norwood, Compliance Officer, at (407) 475-4724.

Sincerely,

A handwritten signature in black ink, which appears to read "Susan M. Turcovski", is positioned above the printed name.

Susan Turcovski
District Director
Florida District

U.S. Food and Drug Administration
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Maitland, Florida 32751
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