



VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

January 31, 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 Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regard to an inspection at a pharmacy licensed by the Florida BOP, Burklow Pharmacy, Inc., located at 4880 Woodbine Road, Pace, FL 32571 (License # PH15761).

FDA inspected the firm from March 2, 2015, to March 4, 2015, to evaluate the firm's processing operations for non-sterile drug products. Florida BOP was informed of the inspection, but did not accompany the FDA investigator during the inspection. 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/UCM440412.pdf>.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Burklow Pharmacy, Inc., 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. Based on our review of the records and the firm's response to Form FDA 483, 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 or by email at Andrea.Norwood@fda.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Turcovski".

A small, stylized handwritten mark or initials, possibly "ST", located to the left of the typed name.

Susan Turcovski
District Director
Florida District

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