FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA UPS NEXT DAY AIR
w/ DELIVERY CONFIRMATION

April 21, 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 you 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 Board of Pharmacy (BOP), Jack P. Herick, Inc. dba Glades Drugs, located at 109 S. Lake Avenue, Pahokee, FL 33476-1803 (License # PH1149).

FDA inspected the firm from November 23, 2015, to December 10, 2015, after receipt of three MedWatch reports dated November 12, 13, and 17, 2015, regarding adverse events experienced by three patients who were hospitalized after ingesting compounded capsules containing vitamin D3 (cholecalciferol) produced by the firm. FDA analysis of samples of the product found that they contained more than 300 times the labeled amount of cholecalciferol per capsule.

Investigators from the Florida State BOP accompanied 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/UCM484600.pdf.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Glades Drugs 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.

FDA issued a warning letter to the firm on August 9, 2016, to address the superpotent compounded cholecalciferol product. After review of the record and the firm's response to the warning letter, it appears that the firm has addressed the violations contained in the warning letter. Glades Drugs advised FDA that it has implemented new standard operating procedures (SOP) related to compounding, including compounding from bulk drug substances, and has also begun random testing of its compounded products. We have reviewed the firm's new SOP and believe that it adequately addresses the issue. FDA does not intend to take further action with

U.S. Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751
www.fda.gov

regard to the findings of this inspection. 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,

Susan Turcovski
District Director
Florida District