

U.S. Food and Drug Administration Kansas City District Office 8050 Marshall Drive - Suite 205 Lenexa, Kansas 66214-1524 913-495-5100

January 10, 2017

Kimberly A. Grinston, Executive Director Missouri State Board of Pharmacy 3605 Missouri Boulevard P.O. Box 625 Jefferson City, MO 65102-0625

Dear Ms. Grinston,

The purpose of this letter is to notify the Missouri 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 Missouri BOP, John's Pharmacy, LLLP, located at 2001 Independence Street, Cape Girardeau, MO 63703 (License #: 2015041869).

FDA inspected the firm from September 6, 2016 to September 7, 2016. Two investigators (Katie DeBold and Barbara Wood) from the Missouri BOP accompanied FDA investigators during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by John's 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 distributes. 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 compounding 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 Eric Mueller, Compliance Officer Kansas City District Office, at (402) 331-8536 (ext.101).

Sincerely,

Cheryl A. Bigham -5 Digitally signed by Cheryl A Bigham S Digitally signed by Cheryl A Bigham S Digitally Signed by Cheryl A Bigham S Digitally Signed Signe

Cheryl Bigham, District Director Kansas City District Office