

Atlanta District 60 Eighth Street NE Atlanta, GA 30309

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February 15, 2017

Tanja Battle, Executive Director Georgia State Board of Pharmacy 2 Peachtree Street NW, 6th Floor Atlanta, GA 30303

Dear Ms. Battle:

The purpose of this letter is to notify the Georgia 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 Georgia BOP, CRC Pharmacy, located at 2500 Hospital Boulevard, Suite 150A, Roswell, GA 30076.

FDA inspected the firm from April 18, 2016, to April 26, 2016, after receiving a MedWatch report related to a drug product compounded by CRC Pharmacy. The Georgia BOP was informed of the inspection but did not accompany FDA investigators during the inspection. During our inspection it was determined that the MedWatch report was not related to a drug product compounded by this pharmacy.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by CRC 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. No Form FDA 483 was issued to the firm at the close of the inspection.

FDA does not intend to take further action with 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 Derek Price, Director of Compliance, 404-253-2277.

Sincerely,

Ingrid Zambrana District Director

Atlanta District Office

Southeast Region, Office of Regulatory Affairs

U.S. Food and Drug Administration