U.S. FOOD & DRUG
ADMINISTRATION

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February 15, 2017

Lee Ann F. Bundrick
Administrator
South Carolina Department of Labor and Licensing – Board of Pharmacy
Kingstree Bldg, 110 Centerview Dr.
Columbia, SC 29210

Dear Ms. Bundrick:

The purpose of this letter is to refer to the South Carolina Department of Labor and Licensing – Board of Pharmacy (BOP) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns observed during an FDA inspection at a pharmacy licensed by the South Carolina BOP, Summerton Drugs Compounding and Dispensary, LLC, dba Summerton Drugs, located at 115B Main Street, Summerton, SC 29148 (License # 9106).

FDA inspected the firm from October 6, 2014, to October 17, 2014, following receipt of a MedWatch report dated July 11, 2014, regarding an adverse event experienced by a patient who received CDBCL-A Cream (3% diclofenac sodium; 2% baclofen; 2% cyclobenzaprine HCl; and 2% lidocaine), a pain cream reportedly compounded by Summerton Drugs. The inspection revealed the product was compounded and dispensed by Innovative Compounding LLC, located in North Carolina (the firm went out of business in August 2014 and transferred its records to Summerton Drugs, which shared the same management). The FDA investigator was accompanied by a South Carolina state investigator for two days. A redacted copy of the 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/UCM432646.pdf.

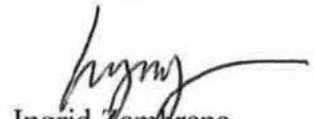
During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Summerton Drugs and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and dispenses.

After review of the records, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified

individual patients, consistent with traditional pharmacy practice, and FDA believes that the firm's pharmacy practice can be appropriately overseen by the State. Therefore, FDA is referring this matter to the South Carolina BOP for follow-up. 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 Branch, via email at derek.price@fda.hhs.gov or by phone at 404-253-2277.

Sincerely,



Ingrid Zambrana
District Director
Atlanta District Office
Southeast Region, Office of Regulatory Affairs
U.S. Food and Drug Administration