DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax:(404) 253-1202 Industry Information: www.fda.gov/oc/industry	10/06/2014 - 10/17/2014*
	FEI NUMBER 3010491410

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ernest F. Phillips, III, Owner and Pharmacist

FIRM NAME	STREET ADDRESS
Summerton Drug Compounding and Dispensary	115 East Main Street
CITY, STATE AND ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Summerton, SC 29148	Producer of Non-Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, the firm failed to investigate the potency failures of Baclofen, Cyclobenzaprine HCl, Diclofenac Sodium, and/or Lidocaine in three lots of CDBCL-A Cream (Lots 11112013@1, 01312014@1, 04182014@5) as required by SOP 9.060, "Product Quarantine, Storage, and Release" and SOP 1.030, "Deviations-OOS" . The Baclofen assay ranged from 84.0%-84.1%; the Cyclobenzaprine HCl assay was 88.0% for each lot, the Diclofenac Sodium assay ranged from 89.0%-90.3%, and the Lidocaine assay ranged from 88.2%-89.0%. The firm's procedures (SOP 9.150, "Non-Sterile Compounding Finished Preparation Testing" and SOP 9.060, "Product Quarantine, Storage, and Release") require that finished product test results conform to specifications but do not include the acceptance criteria. However, SOP 9.140, "Non-Sterile Compounding Process Validation", states the acceptance criteria is as follows: "Potency testing must meet the defined acceptance criteria documented in the USP monograph. If there is no monograph (b) (4) [redacted]."

OBSERVATION 2

The written stability testing program is not followed.

Specifically, there is no stability data to support the current BUDs of 90 days assigned by the firm to the majority of their drug products including CDBCL-A Cream, KBCGL-F Cream, DBCGL-H Cream, and IDCTG Cream. SOP 9.050, "Beyond-Use Dating (BUD) of Compounded Preparations" requires that BUDs shall be assigned on current drug stability information and in the absence of stability information (b) (4) [redacted]

OBSERVATION 3

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, the firm's formula worksheets for CDBCL-A Cream, KBCGL-F Cream, DBCGL-H Cream, and IDCTG Cream do not include complete information relating to the production of the batch including accurate mixing times, the processing

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Penny H. McCarver, Investigator Penny H. McCarver	10/17/2014

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step utilizing the (b) (4) in-process weight checks, visual inspections, correct labeling, or the container used in dispensing. SOP 9.040, "Formula Worksheet", requires the formula compounding worksheet include compounding directions and (b) (4) s. SOP 9.060, "Product Quarantine Storage, and Release", requires that the (b) (4) SOP 9.150, "Non-Sterile Compounding Finished Preparation Testing", requires the finished product to be (b) (4)

OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically, the firm has failed to follow SOP 9.140, "Non-Sterile Compounding Process Validation" which requires (b) (4) validation of the production process (b) (4)

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

The firm failed to follow SOP 9.010, "The Quality Assurance Program". For example, the compliance control officer failed to assure that critical processes are validated; production of drug products is performed in accordance with established procedures; records of each significant step in the process are created/maintained; deviations to procedures are investigated and documented; equipment used is calibrated/maintained in accordance with procedures; and cleaning/sanitization of production areas and equipment are performed/documented.

OBSERVATION 6

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, the firm has failed to follow SOP 3.050, "Cleaning and Maintenance of the Non-Sterile Compounding Area" in that they have no documentation of cleaning for the powder hood, countertops, sinks, or equipment/utensils used in the production of drug products.

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EMPLOYEE(S) SIGNATURE: Patty S. McCarver, Investigator

DATE ISSUED: 10/17/2014

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OBSERVATION 7

The calibration of instruments is not done at suitable intervals in accordance with an established written program and with provisions for remedial action in the event accuracy and/or precision limits are not met.

Specifically, the firm has failed to calibrate the [redacted] (b) (4) balances used to weigh the active ingredients and perform in-process weight checks for their drug products. Additionally, they have no written procedures describing the requirements for the calibration of the balances.

OBSERVATION 8

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,

The firm has failed to follow SOP 5.030, "Complaint Handling", which requires that a "Customer Complaint Record" is to be initiated/documented for each complaint received. Additionally, there is no "Customer Complaint Log" maintained as required by this procedure.

* DATES OF INSPECTION:
10/06/2014(Mon), 10/07/2014(Tue), 10/08/2014(Wed), 10/09/2014(Thu), 10/17/2014(Fri)

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EMPLOYEE(S) SIGNATURE
Peggy D. McCarver, Investigator

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