DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Drive BDLG 200, STE 500 Nashville, TN 37217 (615) 366-7801 Industry Information: www.fda.gov/oc/industry	01/23-26/18; 01/29/18; 02/01/18
	FEI NUMBER 3011504027

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Victor A. Poteet, Co-owner & CEO

FIRM NAME	STREET ADDRESS
The Compounding Pharmacy of America	6216 Highland Place Way, Suite 101-A
CITY, STATE AND ZIP CODE 3011504027	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and 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) (WE) OBSERVED:

Observation 1:

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's large batch media fill consists of (b) (4) vials however your firm routinely produces sterile (b) (4) drug products with batch sizes greater than (b) (4). Examples include but are not limited to the following:

-(b) (4) (lidocaine) which has a batch volume of (b) (4) and is packaged in (b) (4)- 10 ml vials
-Methylcobalamin 1000 MCG/ML which has a batch volume of (b) (4) and is packaged in (b) (4)- 10 ml vials

Observation 2:

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, hormone and non-hormone drug products are prepared and processed in the same rooms (sterile prep area & clean room) using the same equipment ((b) (4) & LAFH). Also, there are no change over cleaning procedures in place to prevent cross-contamination.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Brandon C. Heitmeier	02/01/2018