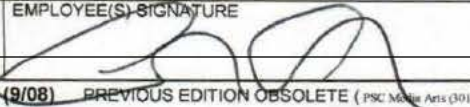


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Cincinnati District Office 6751 Steger Dr Cincinnati 45237 (513) 679-2700		DATE(S) OF INSPECTION 5/13 – 16/2-19	
		FEI NUMBER 3006269306	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED <b>TO: Anne Marie Megibben, Owner</b>			
FIRM NAME Compound Care Pharmacy		STREET ADDRESS 12121 Shelbyville Rd STE 107	
CITY, STATE AND ZIP CODE Louisville, KY 40243		TYPE OF ESTABLISHMENT INSPECTED Sterile Compounding Pharmacy	
<small>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.</small>			
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
<b>OBSERVATION 1</b>			
Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.			
Specifically,			
Your firm does not have assurance that your intrathecal drug products contain safe levels of bacterial endotoxin (BET). The non-sterile active pharmaceutical ingredients (API) baclofen, bupivacaine, clonidine, hydromorphone, and morphine sulfate used in the production of those intrathecal drugs do not contain results for BET testing on their Certificates of Analysis (CoA). Due to this, and combined with the fact that you do not perform testing on your intrathecal drug products – the result is a lack of assurance that your intrathecal products produced with those API are free from BET.			
<hr/>			
<b>OBSERVATION 2</b>			
Disinfecting agents and cleaning pads or wipes used in the ISO 5 area are not sterile.			
Specifically,			
Your firm uses (b) (4) and (b) (4) in your ISO 5 area. Neither of these products is considered self-sterilizing and you do not use sterile versions, or perform sterilization actions on these cleaners. This could result in contamination of your sterile production area by microorganisms and thus risk contamination of your product.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Adam Ross Cooke, Investigator	DATE ISSUED 5/16/2019
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE (PSC Module Arts (301) 443-1090 EF) <b>INSPECTIONAL OBSERVATIONS</b> PAGE 1 of PAGES			