DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Cincinnati District Office 6751 Steger Dr Cincinnati 45237 (513) 679-2700	5/13 – 16/2-19
	FEI NUMBER 3006269306

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Anne Marie Megibben, Owner

FIRM NAME	STREET ADDRESS
Compound Care Pharmacy	12121 Shelbyville Rd STE 107
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Louisville, KY 40243	Sterile Compounding Pharmacy

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

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 pharmacetuical 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.

OBSERVATION 2

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)*	DATE ISSUED
		Adam Ross Cooke, Investigator	**5/16/2019**