DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 781-587-7500 Industry Information: www.fda.gov/oc/industry	06/20-23, 28/2017
	FEI NUMBER 3011430551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: James P. Cangelosi, Owner

FIRM NAME	STREET ADDRESS
Brookfield Pharmacy	60 Old New Milford Rd, Suite 2B
CITY, STATE AND ZIP CODE Brookfield, CT 06804	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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 produces drug products intended for intrathecal use from non-sterile bulk active ingredients that are not controlled for endotoxin level. Therefore, you have no assurance that your final product is within allowable limits for bacterial endotoxins. Intrathecal (IT) drug products manufactured for use in pumps for pain management, such as various combinations of Baclofen, Clonidine, Dilaudid, Ketamine, Fentanyl, Morphine, Sufentanil, Methadone and Bupivacaine, are made with non-sterile bulk drug substances as starting materials e.g. (b) (6), (b) (7)(C) Hydromorphone/Fentanyl/Bupivacaine/Clonidine/Ketamine [hydro - (b) (4), fenta - (b) (4) bupi (b) (4), clonidine (b) (4), and keta - (b) (4)]. Your firm lacks a mechanism for endotoxin control.

OBSERVATION 2

The use of sporicidal agents in the cleanrooms and ISO classified areas are inadequate.

Specifically, your firm references cleaning agents (b) (4) (b) (4)) used to maintain a state of microbial control in your classified areas, where you manufacture intrathecal drug products such as RX (b) (6), (b) (7)(C) Hydromorphone/Bupivacaine/Clonidine ((b) (4)) manufactured 20 JUNE 2017. A review of your firm's cleaning and gowning procedures: SOP #4.01, Cleaning Procedure Rev. 01 and SOP 2.04 Washing and Garbing Rev. 01, revealed that your firm has no stipulation of established contact times for cleaning with a sporicidal agent such as (b) (4) or sanitizing agents such as (b) (4) listed in these SOPs, which your technicians are trained on and use as for guidance while cleaning. The manufacturer's instructions

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Nealie C. Newberger, Investigator Dien N. Nguyen, Investigator	06/28/2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 781-587-7500 Industry Information: www.fda.gov/oc/industry	06/20-23, 28/2017
	FEI NUMBER 3011430551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: James P. Cangelosi, Owner

FIRM NAME	STREET ADDRESS
Brookfield Pharmacy	60 Old New Milford Rd, Suite 2B
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Brookfield, CT 06804	Producer of Sterile and Non-Sterile Drug Products

OBSERVATION 2 continued:

for use of (b) (4) stipulate effective contact times of: (b) (4) for bacterial spores, (b) (4) for bacteria and viruses, (b) (4) for fungi, and (b) (4) for TB. The manufacturer's instructions for use of (b) (4) on gloves stipulates a (b) (4) contact time for sanitization of gloves and hard surfaces. Contact times were not noted to be adhered to during the inspection.

OBSERVATION 3

ISO-5 classified areas were not certified under dynamic conditions. Specifically, uni-directional airflow was not verified under operational conditions.

Specifically, your firm has not executed smoke studies under normal, dynamic working conditions in your classified areas where you manufacture sterile intrathecal drug products such as RX (b) (6), (b) (7)(A) Hydromorphone/ Bupivacaine/Clonidine ((b) (4)) manufactured 20 JUNE 2017.

OBSERVATION 4

The ISO classified areas have difficult to clean, particle-generating, or visibly dirty equipment of surfaces.

Specifically, the pass through between the ISO 8 (b) (4) where products are staged and transferred into the ISO 7 (b) (4) is made of wood with a laminated surface that demonstrates wear marks and unidentified stains. The doors sealing the pass through have a porous foam strip between the door and the frame which has obvious signs of particulate contamination and unidentified staining. Rust was also noted on the legs of the stainless steel preparation table located in the ISO 7 (b) (4) .

Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Nealie C. Newberger, Investigator Dien N. Nguyen, Investigator	06/28/2017