DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	1/18/2023-1/30/2023* FEI NUMBER 3017983596

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Simon D. Castellanos, CEO

FIRM NAME	STREET ADDRESS
Bond Pharmacy dba Advanced Infusion Solutions	18451 Dallas Pkwy , Ste 125
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75287-5212	Producer of 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:

Non-depyrogenated tools were used in sterile drug production.

Specifically,
Your firm uses sterile (b)(4) syringes during aseptic production of your sterile intrathecal injectable drug products however, there is no assurance that the (b)(4) syringes are endotoxin/pyrogen free prior to use in aseptic production. For example:

- Lot (b)(4) was used during aseptic production on (b)(4) but sent for endotoxin testing on (b)(4).

You did not make adequate product evaluation and take remedial action where actionable particle counts were found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically,
Your firm conducts non-viable monitoring of your ISO5 areas (b)(4) and on July 20, 2022, actionable particle counts were obtained in the ISO5 integrated (b)(4) laminar flow hood during aseptic production of sterile intrathecal injectable drug products. Your firm failed to conduct remedial action and there was no assessment performed whether the drug products produced that day were negatively impacted at time of occurrence.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 01-30-2023 10:10: 5	1/30/2023

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Poor cleaning practices observed in ISO5 classified areas.

Specifically,
Your firm's routine cleaning practices are inadequate. For example, on 1/19/2023, poor cleaning practices of (b)(4) located in the ISO5 hoods used to suspend stock solutions during aseptic production were observed by your sterile technicians. I observed your sterile technicians fail to properly disinfect and fully wipe down the underside of the (b)(4).

***DATES OF INSPECTION**
1/18/2023(Wed), 1/19/2023(Thu), 1/20/2023(Fri), 1/23/2023(Mon), 1/24/2023(Tue), 1/30/2023(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 01-30-2023 10:10: 5	1/30/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."