

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 ext 5586 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 6/20 - 7/11/2016
	FEI NUMBER 301231647

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Wanas Khalil

FIRM NAME Queens Express Pharmacy	STREET ADDRESS 34-54 Junction Blvd
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CITY, STATE AND ZIP CODE Jackson Heights, NY 11372	TYPE OF ESTABLISHMENT INSPECTED Pharmaceutical Outsourcing Facility
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient will regarding the system for monitoring environmental conditions.

Specifically:

Viable surface sampling using (b) (4) is conducted (b) (4) and may or may not be conducted on days when operations in the cleanroom occur. Further, we noted that sampling could potentially result in residual media left on the LAF surface and this would have to be cleaned off before resuming operations. The QA manager stated that the technician would do this, however, there are no written instructions which address this operation.

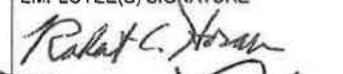

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically:

- a) Personnel monitoring is limited to fingertip sampling with (b) (4).
- b) Drug product vials and diluent bags are transferred from the storage room to the compounding suite where they are (b) (4) with a (b) (4) and wiped with sterile (b) (4); no contact time established.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE (Print or Type) Robert C. Horan, Ph.D., Investigator DEMETRIA JENNY XIRADAKIS, INVESTIGATOR	DATE ISSUED 7/11/2016 7/11/2016
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OBSERVATION 3

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically:

Inspection of the compounding suite found that the gloves available to cleanroom personnel were from a manufacturer which reportedly had been removed four months prior from the firm's approved material list due to the gloves tearing and needing to be replaced frequently during operations in the ISO 5 area. The verbal response from management was that they had run out of the (b) (4) gloves which had replaced the discontinued sterile gloves from (b) (4)

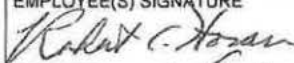

OBSERVATION 4

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically:

The smoke study conducted by contractor and documented in a video was found to (b) (4). The smoke study was not conducted under dynamic conditions representative of the activities conducted in the LAF and with the maximum number of employees performing routine operations. A sign on the cleanroom door states that maximum number of employees is (b) (4). In addition, while the LAF observed in the smoke study video contained no other materials, observation of actual operations in the cleanroom found that the technician working closely with the technician responsible for operations in the LAF (b) (4).

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OBSERVATION 5

Drug products are not stored under appropriate conditions of temperature so that their identity, strength, quality, and purity are not affected.

Specifically:

There is no documented monitoring of temperature in the (b) (4) rooms employed for storage of drug product vials and drug products. On 7/6/2016, examination of (b) (4) thermometers employed in those rooms found the temperature to be 84°F in the drug product storage room and 79°F in the room used for storage of drug product vials. Products observed to be stored in the final drug product storage room include:

- Piperacillin-Tazobactam 4.5 gm in 100 mL D5W, lot 16060970
- Vancomycin 1 gm in 250 mL D5W, lot 16060756
- Ampicillin/ Sulbactam 3 gm in 100 mL NSS, lot 16061183
- Unasyn 3 gm in 100 mL NSS, lot 16061610

7/11/2016 RCT

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	<i>D. Jerry Ximopoulos</i>	D. Jerry Ximopoulos, Investigator	7/11/2016