

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

DISTRICT ADDRESS AND PHONE NUMBER

158-15 Liberty Avenue
Jamaica, NY 11433
(718) 340-7000 Ext:5301 Fax: (718) 662-5661
ORAPHARM1_RESPONSES@fda.hhs.gov

DATE(S) OF INSPECTION

9/21/2021-11/4/2021*

FEI NUMBER

3010840309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Sarah J. McCoy, Director, Plant Operations

FIRM NAME

SterRx, LLC

STREET ADDRESS

141 Idaho Ave

CITY, STATE, ZIP CODE, COUNTRY

Plattsburgh, NY 12903-3987

TYPE ESTABLISHMENT INSPECTED

Outsourcing Facility 503B

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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under (b) (4) pressure.

Specifically:

1. Blow-Fill-Seal (BFS) operations in your (b) (4) process, including (b) (4) and shuttling of the (b) (4) to the point of aseptic filling, are conducted under air supplied at lesser quality than ISO 5. (b) (4) are exposed during (b) (4) and shuttling within the ISO 7 classified zone to the point of aseptic filling in BFS machines BFS (b) (4) Equipment # (b) (4) and BFS (b) (4), Equipment # (b) (4)

Furthermore, you have not evaluated the airflow pattern and airborne particulates in the critical processing zones during operation of BFS machines BFS (b) (4) and BFS (b) (4) where (b) (4) and the (b) (4) are shuttled to the point of aseptic filling.

BFS (b) (4) is used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022.

BFS (b) (4) is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

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Edmund F Mrak, Investigator
Lori M Newman, Investigator

DATE ISSUED

11/4/2021

Edmund F Mrak
Investigator
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Date Signed: 11-04-2021
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2. The design and construction of the IV Bag filling line, Equipment # (b) (4) and its enclosure do not provide first pass HEPA-filtered laminar flow air over all critical areas within the ISO 5 classified zone as follows:
 - a. Your dynamic airflow pattern study conducted under protocol PR-2018-187 (b) (4) and reported in RPT-2018-187- (b) (4) Bag Filling and Sealing Machine (b) (4) Smoke Study, identified turbulence and upward flow of air near Fill Station (b) (4). This airflow condition was accepted and approved on 10/15/2019 by your firm management without attempting corrective actions.
 - b. Direct coverage by first pass HEPA-filtered laminar flow air is not provided over the filling side of the (b) (4) Bag Filling and Sealing Machine where open IV bags are (b) (4) removed from wrapping and exposed, held, and passed to the filling section of the line.
 - c. First pass HEPA-filtered laminar flow air is blocked by the “(b) (4)” over approximately one half of the (b) (4) bowl and the track system (b) (4) to the filling side of the (b) (4) Bag Filling and Sealing Machine. Furthermore, your airflow pattern study reported in RPT-2018-187- (b) (4) Bag Filling and Sealing Machine (b) (4) Smoke Study, did not evaluate the airflow pattern in the area of the (b) (4) bowl and track system where it is obstructed by the (b) (4).

The IV Bag filling line, Equipment # (b) (4) is used to produce drug products intended to be sterile including Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: (b) (4) packaged as Lot: (b) (4), Released: 05/07/2021, Expiration Date: 11/19/2021.

3. First pass HEPA-filtered laminar flow air is obstructed by the (b) (4) and (b) (4) and the (b) (4) bowl over open, partial bags of syringe plungers held adjacent to the (b) (4) bowl

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used to hold and convey plungers on the aseptic syringe filling system (b) (4)
 Equipment # (b) (4) The (b) (4), Equipment # (b) (4), is used to produce drug products intended to be sterile including 200 mg Succinylcholine Chloride Injection 10mL (20 mg/mL), Batch: (b) (4) filled on 09/24/2021.

OBSERVATION 2

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically:

You do not maintain the sterility of the cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing sterile drug products. Furthermore, the container closure is not designed such that the user can sanitize the surface(s) before spiking for administration to a patient. More specifically:

1. The cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing drug products produced in BFS (b) (4) Equipment # (b) (4) are not maintained sterile. Filled BFS IV bags produced in BFS (b) (4) are (b) (4) offloaded from a conveyor and held in an ISO 7 classified area prior to capping. The capping process includes sanitization of the BFS IV bag tops with (b) (4) (b) (4) before capping under ISO 7 conditions. BFS (b) (4) and the offline capping system are used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection,

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Batch: (b) (4) packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022.

2. The cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing drug products produced in BFS (b) (4), Equipment # (b) (4) are not maintained sterile and are exposed to less than ISO 5 environmental conditions. BFS IV bags containing drug products produced in BFS (b) (4) are conveyed and capped (b) (4) under ISO 7 classified conditions. BFS (b) (4), Equipment # (b) (4) is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

OBSERVATION 3

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

Specifically:

1. Your surface and airborne viable monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. Your firm's procedures permit surface and air samples from within ISO 5 environments to yield microbiological contaminants of (b) (4) without conducting an investigation. More specifically:
 - a. Prior to revision in August 2021 your environmental monitoring plans and specifications for surface viable monitoring permitted (b) (4) microbial recoveries on filling needles and mandrels (BFS) in the critical filling zones of the IV Bag filling line, Equipment # (b) (4) Syringe Line, Equipment # (b) (4) BFS (b) (4) Equipment # (b) (4) and BFS (b) (4) (b) (4) Equipment # (b) (4) without requirements for investigation and action. For example:

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- i. Your environmental monitoring plan, Environmental Monitoring – Bag Filler (b) (4) permitted (b) (4) microbial recoveries on filling needles in the critical filling zone of the IV Bag filling line, Equipment # (b) (4) Your environmental monitoring record for filling Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the IV Bag filling line, Equipment # (b) (4) shows that “Post Batch Bag Filler Sampling – ISO 5” performed on 03/24/2021 recovered (b) (4) from the surface of the right filling needle. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/07/2021, Expiration Date: 11/19/2021.
- ii. Your environmental monitoring plan, Environmental Monitoring – Syringe Line, permitted (b) (4) microbial recoveries on filling needles in the critical filling zone of the Syringe Line, Equipment # (b) (4) Your environmental monitoring record for filling Succinylcholine 20mg/ml in 0.4% Sodium Chloride – 10ml Pre-Filled Syringe, Batch: (b) (4) , Environmental Monitoring Lot: (b) (4) on the Syringe Line, Equipment # (b) (4) shows that “Post Batch Syringe Line Sampling – ISO 5” performed on 04/06/2020 recovered (b) (4) from the surface of the (b) (4) filling needle. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/20/2020, Expiration Date: 07/05/2020.
- iii. Your environmental monitoring plans, Environmental Monitoring – ISO 7 (b) (4) and ISO 8 Fill Room (b) (4) and Environmental Monitoring – ISO 8 Cleanroom, permitted (b) (4) microbial recoveries on filling mandrels in the critical filling zone of the BFS (b) (4) , Equipment # (b) (4) Your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml

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in 5% Dextrose Injection, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the BFS (b) (4) Equipment # (b) (4) shows that "Post Batch BFS (b) (4) Fill Zone Sampling – ISO 5" performed on 04/27/2021 recovered 1 CFU from the surface of the (b) (4) Mandrel From the Front – Left Side. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/21/2021, Expiration Date: 03/23/2022.

Additionally, your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) 0 on the BFS (b) (4), Equipment # (b) (4) shows that "Post Batch BFS (b) (4) Fill Zone Sampling – ISO 5" performed on 01/13/2021 recovered 1 CFU from the surface of the (b) (4) Mandrel – Right Side. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 02/17/2021, Expiration Date: 12/09/2021.

iv. Your environmental monitoring plan, Environmental Monitoring – ISO 7 Cleanroom with Sanitization (b) (4), permitted (b) (4) microbial recoveries on filling mandrels in the critical filling zone of the BFS (b) (4) Equipment # (b) (4). Your environmental monitoring record for filling Norepinephrine 8mg in 0.9% Sodium Chloride Injection-250ml, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the BFS (b) (4) Equipment # (b) (4) shows that "Post Batch Fill Zone Sampling – ISO 5" performed on 01/16/2020 recovered 1 CFU from the surface of the (b) (4) Mandrel – (b) (4). You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 04/09/2020, Expiration Date: 08/22/2020.

b. Your current environmental monitoring plans and specifications for airborne and surface viable monitoring permit (b) (4) recoveries within the ISO 5 classified zones inside the enclosures of the IV Bag filling line, Equipment # (b) (4) and Syringe Line, Equipment #

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(b) (4) without requirements for investigation and action. For example:

i. Your Work Instruction WI-MCB-0017 for drug products filled on the IV Bag filling line, Equipment # **(b) (4)** permits surface and air samples from within ISO 5 environment to yield microbiological contaminants of **(b) (4)** without investigation and action. For example:

1. Your environmental monitoring record for filling Midazolam 1mg/ml in 0.9% Sodium Chloride, 50ml fill in 100ml IV Bag, Batch: **(b) (4)** Environmental Monitoring Lot: **(b) (4)** on the IV Bag filling line, Equipment # **(b) (4)** shows that "Post Batch Bag Filler Sampling – ISO 5" performed on 04/07/2021 recovered 1 CFU from the surface of the Bag Filler Interior, Filling Side Interior Plexiglass Left. You did not investigate or take any other action, and the batch was packaged as Lot: **(b) (4)**, Released: 05/07/2021, Expiration Date: 12/02/2021.
2. Your environmental monitoring record for filling 150 mEq Sodium Bicarbonate in 5% Dextrose Injection, 1000ml, Batch: **(b) (4)** Environmental Monitoring Lot: **(b) (4)** on the IV Bag filling line, Equipment # **(b) (4)** shows that airborne viable monitoring "During the Batch Bag Filler Sampling – ISO 5" performed on 04/23/2020 recovered 1 CFU from the Bag Filler Side. You did not investigate or take any other action, and the batch was packaged as Lot: **(b) (4)**, Released: 05/13/2020, Expiration Date: 03/18/2021.

ii. Your Work Instruction WI-MCB-0012 for drug products filled on the Syringe Line, Equipment # **(b) (4)** permits surface and air samples from within the ISO 5 environment to yield microbiological contaminants of **(b) (4)** without investigation

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and action.

c. Your current environmental monitoring plans and specifications for airborne viable monitoring permit (b) (4) recoveries in the critical filling zones of BFS (b) (4) Equipment # (b) (4) and BFS (b) (4) , Equipment # (b) (4) without requirements for investigation and action. For example:

i. Your Work Instruction WI-MCB-0009 for drug products filled on BFS (b) (4) Equipment # (b) (4) permits air samples from within the ISO 5 Fill Zone to yield microbiological contaminants of (b) (4) without investigation and action. For example:

1. Your environmental monitoring record for filling 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the BFS (b) (4) Equipment # (b) (4) shows that airborne viable monitoring "During the Batch Fill Zone Sampling – ISO 5" performed on 04/05/2021 recovered 1 CFU from the Fill Zone (b) (4). You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022

ii. Your Work Instruction WI-MCB-0011 for drug products filled on BFS (b) (4) , Equipment # (b) (4) permits air samples from within the ISO 5 Fill Zone to yield microbiological contaminants of (b) (4) without investigation and action. For example:

1. Your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) Environmental

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Monitoring Lot: (b) (4) on the BFS (b) (4), Equipment # (b) (4) shows that airborne viable monitoring "Post Batch BFS (b) (4) Fill Zone Sampling – ISO 5" performed on 02/01/2021 recovered 1 CFU from the from the Fill Zone (b) (4). You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

2. Your airborne particulate monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. You do not monitor airborne particulates to ISO 5 air classifications in all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in monitored locations. For example:
 - a. Airborne particulate monitoring of filling operations on the IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) does not include all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in monitored locations. More specifically:
 - i. You do not monitor airborne particulates in close proximity to open IV bags that are (b) (4) unwrapped and held for filling.
 - ii. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the filler side and the injection port feed side pre-batch filling (b) (4) according to your Work Instruction WI-MCB-0017.
 - iii. The orientation of particle counter probes is not directed into the flow of air in monitored locations near the filler and the port bowl and track.

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Furthermore, your specifications written in Work Instruction WI-MCB-0017 and batch monitoring records for airborne particle counts taken on the filler side of the IV Bag filling line during filling of 150mEq Sodium Bicarbonate in 5% Dextrose Injection and 125mg Diltiazem D5W / 125mg Diltiazem 0.7% Sodium Chloride Injection do not meet clean area air classifications for ISO 5 as follows:

- 150mEq Sodium Bicarbonate in 5% Dextrose Injection:
 - (b) (4) μm Alert \geq (b) (4) particles/ft³
 - (b) (4) μm Action: \geq (b) (4) particle/ft³

- 125mg Diltiazem D5W / 125mg Diltiazem 0.7% Sodium Chloride Injection:
 - (b) (4) μm Alert \geq (b) (4) particle/ft³
 - (b) (4) μm Action \geq (b) (4) particle/ft³

You do not investigate excursions over ISO 5 air classifications that are within your internal specifications shown above. For example: Your environmental monitoring record for filling 125 mg Diltiazem D5W/125mg Diltiazem 0.7% Sodium Chloride, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) shows that "During the Batch Bag Filler Sampling – ISO 5" performed on (b) (4) 06/24/2021 resulted in 160.0 particles/ft³ over (b) (4) μm . This result exceeds limits established in ISO 5 air classifications, but it was deemed acceptable in accordance with your internal specifications and there were no actions taken. The batch was packaged as Lot: (b) (4), Released: 07/28/2021, Expiration Date: 02/19/2022.

b. Airborne particulate monitoring of filling operations on the aseptic syringe filling system,

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FIRM NAME SterRx, LLC	STREET ADDRESS 141 Idaho Ave
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CITY, STATE, ZIP CODE, COUNTRY Plattsburgh, NY 12903-3987	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility 503B
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(b) (4)
Equipment # (b) (4) does not include all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in the monitored location. More specifically:

- i. You do not monitor airborne particulates in close proximity to the (b) (4) bowl and track.
- ii. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the syringe filling system (b) (4) pre-batch filling (b) (4) according to your Work Instruction WI-MCB-0012.
- iii. The orientation of the (b) (4) is not directed into the flow of air in the monitored location near the filler head.

The (b) (4), Equipment # (b) (4) is used to produce drug products intended to be sterile including 200 mg Succinylcholine Chloride Injection 10mL (20 mg/mL), Batch: (b) (4) filled on 09/24/2021.

- c. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the critical filling zone of BFS (b) (4) Equipment # (b) (4) (b) (4) according to your Work Instruction WI-MCB-0009 and batch monitoring records.

Furthermore, your specifications written in Work Instruction WI-MCB-0009 and batch monitoring records for airborne particle count of (b) (4) μm Alert > (b) (4) particles/ft³, Action >

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

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9/21/2021-11/4/2021*

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(b) (4) particles/ft³, in the critical filling zone of BFS (b) (4) Equipment # (b) (4) do not meet clean area air classifications for ISO 5. No corrective actions are taken for excursions over ISO 5 air classifications that are within your internal specifications. For example: Your environmental monitoring record for filling 4 mg Norepinephrine in 0.9% Sodium Chloride Injection 250 mL (16 mcg/ml) BFS IV Bag, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) in BFS (b) (4) shows that "During the Batch Fill Zone Sampling – ISO 5" initial performed on 09/09/2021 resulted in 359.0 particles/ft³ over (b) (4) μm and the end of batch result was 502.0 particles/ft³ over (b) (4) μm. These results exceed the limits established in Class 100 / ISO 5 air classifications, but they were deemed acceptable in accordance with your internal specifications and there were no actions taken. The batch was packaged as Lot: (b) (4) Released: 09/29/2021, Expiration Date: 09/04/2022.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically:

The design and construction of BFS (b) (4) Equipment # (b) (4) incorporates machine parts that are particle generating and difficult to sanitize within the ISO 7 classified zone of your (b) (4) process equipment. During the inspection we observed the following within the ISO 7 Classified shrouded area of BFS (b) (4) painted machine parts were chipped and missing paint; the machine frame had signs of surface corrosion; wiring was hanging and secured with tape; tubing was hanging; and there was a build-up of resin residues. Additionally, tubing and wiring are not routed and secured in a manner to prevent chaffing and particle generation. The ISO 7 classified area where these conditions were observed houses the critical processing zone of BFS (b) (4) where (b) (4) are shuttled to the point of aseptic filling. BFS (b) (4) is used to produce drug products intended to be sterile including 20mg

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Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch (b) (4), packaged as Lot: (b) (4),
Released: 04/30/2021, Expiration Date: 01/30/2022.

OBSERVATION 5

Substances required for equipment operations such as lubricants and coolants come in contact with components and closures so as to alter the safety, identity, strength, quality or purity of the drug product beyond the official or other established requirements.

Specifically:

On the IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) you have not evaluated whether or to what extent solvents and lubricants contained in (b) (4) spray applied to the (b) (4) bowl transfer to and contaminate IV Bag closures (ports). In accordance with your manufacturing batch records, during setup and operation of IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) you apply (b) (4) spray onto the stainless-steel (b) (4) bowl to (b) (4) . Your manufacturing batch records indicate that the machine may be stopped during the filling operation and "(b) (4) ". The IV Bag filling line, Equipment # (b) (4) is used to produce drug products intended to be sterile including Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: (b) (4), packaged as Lot: (b) (4), Released: 05/07/2021, Expiration Date: 11/19/2021.

OBSERVATION 6

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There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically:

You lack complete information about the environmental conditions in critical areas during aseptic filling operations necessary for investigation and determination of the full product impact and root cause of environmental excursions and drug product sterility failures. Furthermore, your lack of complete environmental data and root cause identification diminishes your ability to determine and implement effective corrective and preventive actions. For example:

1. Since June 2019 you have reported three drug product sterility failures for lots produced on the IV Bag filling line, Equipment # (b) (4) Conclusions from your investigations are as follows:
 - a. Your investigation, MIR-2019-350, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on (b) (4), out of specification (OOS) results for Particulate Matter per USP<788> and Not Sterile per USP<71>, was inconclusive. Organisms recovered were identified as *Herbaspirillum huttiense* and *Burkholderia multivorans*. The batch was rejected. There was no assignable cause determined and no CAPA initiated. Your investigation failed to attempt identification of the particulate matter in the drug product samples and use such information to assist in determining the root cause of the event and effective CAPA. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # (b) (4) and equipment design deficiencies affecting airflow in critical areas contributed to this event.
 - b. Your investigation, MIR-2020-008, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on (b) (4) OOS result Not Sterile per USP<71>, identified inadequate methods for cleaning and sanitization of the IV Bag filling line following maintenance interventions. The organism recovered was identified as

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Burkholderia multivorans. The batch was rejected. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # (b) (4) and equipment design deficiencies affecting airflow in critical areas contributed to this event.

- c. Your investigation, MIR-2020-127, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on (b) (4), OOS result Not Sterile per USP<71>, was inconclusive. The batch was rejected. Although there was no assignable cause attributable to the contract laboratory your investigation concluded that the most likely cause of this event was contamination during testing since the analyst performed (b) (4) tests on the day that the subject sample was tested, and the organism (*Staphylococcus epidermidis*) only grew in one media. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # (b) (4) and equipment design deficiencies affecting airflow in critical areas contributed to this event.
2. Your investigation, MIR-2020-099, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on BFS (b) (4) Equipment # (b) (4) on 03/18 -19/2020, OOS result Not Sterile per USP<71>, was inconclusive. The organism recovered was identified as *Bacillus subtilis*. The batch was rejected. There was no assignable cause determined and no CAPA initiated. Your investigation failed to identify the BFS (b) (4) Equipment # (b) (4) condition and inadequate environmental monitoring program as potentially contributing to this event.
3. Your investigations including MIR-2021-310, MIR-2021-421, and MIR-2021-463 in response to airborne particle count exceeding action limits in the critical zone of the IV Bag filling line, Equipment # (b) (4) conclude that multiple equipment related issues inherent to the filling process on the IV Bag filling line are the root cause of the subject events. You determined that there was no product impact resulting from these events due to acceptable viable monitoring results, visual inspection results, and finished product release testing results and all batches/lots implicated in these

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investigations were released in full. You did not determine and implement effective preventive actions to control generation of particulate contamination within the ISO 5 classified zone of the IV Bag filling line, Equipment # (b) (4). Furthermore, although your records indicate that drug products produced during periods of high particle count generation were segregated by the Packaging Unit, your Quality Unit did not issue a hold status or otherwise control the implicated (segregated) product and require additional consideration for its disposition.

For example:

- a. Your investigation, MIR-2021-310, was written for three events of over-action in-process particle counts on the IV Bag filling line, Equipment # (b) (4) during production of drug products as follows:
 - i. On 06/03/2021, in-process environmental monitoring detected 708.0 particles/ft³ over (b) (4) μm, exceeding the Action Limit: (b) (4) particles/ft³ over (b) (4) μm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 125 mg Diltiazem D5W/125mg Diltiazem 0.7% Sodium Chloride Batch: (b) (4) Lot: (b) (4), Released: 07/14/2021, Expiration Date: 01/28/2022.
 - ii. On 06/15/2021, in-process environmental monitoring detected 119.0 particles/ft³ over (b) (4) μm, exceeding the Action Limit: ≤ (b) (4) particles/ft³ over (b) (4) μm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 100 mg Morphine Sulfate 1 mg/ml in 5% Dextrose 100 ml, Batch: (b) (4) , Lot: (b) (4), Released: 07/08/2021, Expiration Date: 12/12/2021.
 - iii. On 06/17/2021, in-process environmental monitoring detected 143.0 particles/ft³ over (b) (4) μm, exceeding the Action Limit: ≤ (b) (4) particles/ft³ over (b) (4) μm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg/ml Midazolam in 0.9% Sodium Chloride 100 ml, Batch: (b) (4) Lot: (b) (4), Released: 07/28/2021, Expiration Date: 02/12/2022.

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Your investigation, MIR-2021-310, concluded that multiple equipment malfunctions including (b) (4)

(b) (4) are the root cause of these overaction limit particle counts. You determined, without adequate justification, that there is no product impact as a result of these over-action in-process particle count events and you released each lot in full for distribution.

- b. Your investigation, MIR-2021-421, was written for four events of over-action in-process particle counts (Action Limit: \leq (b) (4) particles/ft³ over (b) (4) μ m) on the IV Bag filling line, Equipment # (b) (4) during production of drug products as follows:
- i. On 07/27/2021, in-process environmental monitoring detected 102.0 particles/ft³ over (b) (4) μ m on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: (b) (4), Lot: (b) (4), Released: 08/30/2021, Expiration Date: 03/23/2022. Your investigation concluded that the (b) (4) (b) (4). This implies that the filling system and designed flow of HEPA filtered air is incapable of excluding particles generated on the component side from the filling side near the filling needles. You determined, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and you released the lot in full for distribution.
 - ii. On 08/02/2021, in-process environmental monitoring detected 108.0 particles/ft³ over (b) (4) μ m on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 2.5 mg Fentanyl in 0.9% Sodium Chloride Injection 250 ml (10 mcg/ml) Batch: (b) (4) Lot: (b) (4), Released: 08/30/2021, Expiration Date: 03/30/2022. Your investigation concluded that (b) (4) (b) (4). You determined, without adequate justification, that there is no product impact as a

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result of this over-action in-process particle count event and you released the lot in full for distribution.

iii. On 08/04/2021, in-process environmental monitoring detected 162.0 particles/ft³ over ^{(b) (4)} μm on the filling side of the IV Bag filling line, Equipment # ^{(b) (4)} while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: ^{(b) (4)}, Lot: ^{(b) (4)}, Released: 09/08/2021, Expiration Date: 04/01/2022. There were no corrective actions reported in your investigation. You determined, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and you released the lot in full for distribution.

iv. On 08/11/2021, in-process environmental monitoring detected 103.0 particles/ft³ over ^{(b) (4)} μm on the filling side of the IV Bag filling line, Equipment # ^{(b) (4)} while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: ^{(b) (4)} Lot: ^{(b) (4)}. Your investigation concluded that particles were generated in the filler zone due to ^{(b) (4)}

^{(b) (4)}. Your investigation concluded, witho ut adequate justification, that there is no product impact as a result of this over-action in-process particle count event and disposition of the subject lot is pending review.

c. Your investigation, MIR-2021-463, was written for two events of over-action in-process particle counts on the IV Bag filling line, Equipment # ^{(b) (4)} during production of drug products as follows:

i. On 08/20/2021, in-process environmental monitoring detected 894.0 particles/ft³ over ^{(b) (4)} μm, exceeding the Action Limit: ≤ ^{(b) (4)} particles/ft³ over ^{(b) (4)} μm, on the filling side of the IV Bag filling line, Equipment # ^{(b) (4)} while filling 1 mg/ml Midazolam in 0.9% Sodium Chloride 100 ml, Batch: ^{(b) (4)}, Lot: ^{(b) (4)}.

ii. On 08/23/2021, in-process environmental monitoring detected 148.0 particles/ft³ over ^{(b) (4)} μm, exceeding the Action Limit: ≤ ^{(b) (4)} particles/ft³ over ^{(b) (4)} μm, on the filling side of the IV Bag filling line, Equipment # ^{(b) (4)} while filling 1 mg/ml

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Midazolam in 0.9% Sodium Chloride 100 ml, Batch: (b) (4), Lot: (b) (4).

Your investigation, MIR-2021-463, determined that (b) (4) including a (b) (4) are the root cause of these overaction limit particle counts. Your investigation concluded, without adequate justification, that there is no product impact as a result of these overaction in-process particle count events and disposition of the subject lots is pending review.

OBSERVATION 7

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically:

Equipment used on the IV bag filling line #(b) (4) including drug product component contact change parts and utensils required to be sterile is not adequately protected from contamination before use. Equipment and change parts used in production in the ISO 5 classified zone of the IV bag filling line, such as the utensil box, tweezers, scoop, and (b) (4) bowl is sterilized in (b) (4) (b) (4) #(b) (4). This (b) (4) is situated in an unclassified area adjacent to the process (b) (4) production area. Per SOP PRD213, "Sterilization of Bag Filler Components and Equipment in (b) (4)" the equipment is (b) (4) wrapped in "(b) (4) or equivalent" prior to sterilization in the (b) (4) and any rips in the outer foil layer may be repaired with (b) (4) tape. After the wrapped equipment is sterilized, it is removed from the (b) (4) and placed on a transfer cart, the cart is moved to the controlled unclassified "transition area," and the outer layer of foil is sprayed with sterile (b) (4)

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The SOP does not specify for how long the equipment may remain in the transition zone wrapped in foil prior to use.

OBSERVATION 8

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically:

1. You have not validated (b) (4) in BFS machines BFS (b) (4) Equipment # (b) (4) and BFS (b) (4), Equipment # (b) (4) More specifically you have not validated that time temperature conditions of the (b) (4) process are effective against endotoxin or spore challenges in the (b) (4) material that makes up the drug product primary container closure.

BFS (b) (4) is used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022.

BFS (b) (4) is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4), packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

2. Operators are permitted to participate in aseptic production on a given line prior to completing a successful aseptic simulation on that line. For example:

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Plattsburgh, NY 12903-3987

TYPE ESTABLISHMENT INSPECTED

Outsourcing Facility 503B

- a. Operator ^{(b) (6)} participated in the production of commercial sodium bicarbonate batches ^{(b) (4)} in June 2019 and ^{(b) (4)} in July 2019 on the IV bag filling line # ^{(b) (4)}. One of ^{(b) (6)} roles is to spray the outer package of the sterile IV bags with sterile ^{(b) (4)} and place the package in the material ^{(b) (4)} adjacent to the bag filling station, as documented in step ^{(b) (4)} of batch ^{(b) (4)}. The only aseptic simulation documented in ^{(b) (6)}'s training record was on the syringe line # ^{(b) (4)} on January 27, 2021. This occurred both after ^{(b) (6)} participated in commercial aseptic production on the IV bag filler in 2019 and on a different production line (syringe line # ^{(b) (4)}). No documentation of ^{(b) (6)} participating in an aseptic simulation on the IV bag filling line # ^{(b) (4)} has been provided.
- b. Operator ^{(b) (6)} participated in the production of commercial sodium bicarbonate batches ^{(b) (4)} and ^{(b) (4)} in March 2019 on the IV bag filling line # ^{(b) (4)}. One of ^{(b) (6)} roles on this line is collecting ^{(b) (4)} bioburden samples, as documented in step ^{(b) (4)} of batch ^{(b) (4)}. ^{(b) (6)} completed an aseptic simulation on this line in September 2019, after the batches were produced in March 2019. Thus, ^{(b) (6)} participated in aseptic production prior to participating in an aseptic simulation for that production line.

OBSERVATION 9

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically:

You permit personnel to enter packaging areas and conduct packaging operations in their street clothes and footwear. Your Change Control, CC No. CC-2020-043, approved on 04/09/2020, permitted temporary deviation from your procedure ADM102, Facility and Gowning, due to a shortage of supplies. During the inspection on 09/22/2021 we observed packaging and inspection personnel dressed

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EMPLOYEE(S) SIGNATURE

Edmund F Mrak, Investigator
Lori M Newman, Investigator

DATE ISSUED

11/4/2021

Edmund F Mrak
Investigator
Signed By: Edmund F. Mrak, Jr -6
Date Signed: 11-0-2021
12:58:0

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

DISTRICT ADDRESS AND PHONE NUMBER

158-15 Liberty Avenue
Jamaica, NY 11433
(718) 340-7000 Ext:5301 Fax: (718) 662-5661
ORAPHARM1_RESPONSES@fda.hhs.gov

DATE(S) OF INSPECTION

9/21/2021-11/4/2021*

FEI NUMBER

3010840309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Sarah J. McCoy, Director, Plant Operations

FIRM NAME

SterRx, LLC

STREET ADDRESS

141 Idaho Ave

CITY, STATE, ZIP CODE, COUNTRY

Plattsburgh, NY 12903-3987

TYPE ESTABLISHMENT INSPECTED

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in street clothes and personal footwear handling BFS IV bags containing 150 mEq Sodium Bicarbonate in 5% Dextrose Injection 1,000 mL (12.6mg/mL) BFS IV Bag, Batch # (b) (4) in controlled unclassified Packaging Room (b) (4) Personnel in street clothes, handled the drug product for visual inspection and insertion of the BFS IV bags into secondary packaging (pouches) before sealing.

OBSERVATION 10

The written stability program for drug products does not include meaningful test methods.

Specifically:

Your stability program SOP-VAL-0097 does not evaluate the photostability of light-sensitive drug products in the marketed packaging. Examples of such products are 2 mg epinephrine in 0.9% sodium chloride injection 250 mL (8 mcg/mL) and 1 mg fentanyl in 0.9% sodium chloride injection 100 mL (10 mcg/mL). Although in accordance with your protocols the stability samples remain within their marketed secondary packaging consisting of foil-lined pouches throughout the hold time, your firm lacks sufficient evidence through direct testing to show that the secondary packaging adequately protects drug products from light.

OBSERVATION 11

Employees are not given training in the particular operations they perform as part of their function.

Specifically:

- Investigation MIR-2020-008 states that a root cause of the sterility failure for 150 mEq sodium bicarbonate in 5% dextrose batch (b) (4) /Lot (b) (4), manufactured (b) (4), was a lack of

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Edmund F Mrak, Investigator
Lori M Newman, Investigator

DATE ISSUED

11/4/2021

Edmund F Mrak
Investigator
Signed By: Edmund F. Mrak, Jr -6
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 9/21/2021-11/4/2021*
	FBI NUMBER 3010840309

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sarah J. McCoy, Director, Plant Operations

FIRM NAME SterRx, LLC	STREET ADDRESS 141 Idaho Ave
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CITY, STATE, ZIP CODE, COUNTRY Plattsburgh, NY 12903-3987	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility 503B
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training of an operator (b) (6) participating in the aseptic production of that batch. The batch was produced on IV Bag filling line #(b) (4) and the organism was identified as *Burkholderia multivorans*. MIR-2019-394 was opened to address (b) (6) production activities prior to training. It indicates that (b) (6) did not complete the prerequisite training module MOD00002 "General GMP" until 12/23/19, 10 days after (b) (6) participated in batch production. This practice conflicts with your SOP QAS 209 "Training Program," which states, "Employees, consultants, interns and contractors will be trained on procedures required to perform their job functions prior to performing the tasks described in the procedure."

- Operator (b) (6) participated in the production of commercial sodium bicarbonate batches (b) (4) and (b) (4) on the IV bag filling line ((b) (4)) in March 2019. (b) (6) training record shows that (b) (6) was "first trained" to operate the bag filling line in early March 2019 but was not considered "fully trained" until September 6, 2019, which is after batches (b) (4) and (b) (4) were produced. Training form TRN00114-ASSESS (Version A) defines "first training" as watching the activity, and "full training" as performing the activity independently and accurately. Thus, (b) (6) participated in aseptic production prior to being certified to perform production independently and accurately.

OBSERVATION 12

Complaint records are deficient in that they do not include the known reply to complainant.

Specifically:

Complainants do not always receive a final written response to their drug product complaint. For instance, you have received complaints for four adverse events since the last inspection and investigated these, but your records do not include a final written response to the complainant regarding investigation findings. Firm management confirmed that a written response was not issued. SOP QAS205 "Customer Complaints and Adverse Events" also does not require a written response to the complainant.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Edmund F Mrak, Investigator Lori M Newman, Investigator	Edmund F Mrak Investigator Signed By: Edmund F. Mrak, Jr -6 Date Signed: 11-0 -2021 12:58:0 X	DATE ISSUED 11/4/2021

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Some complaint records do include e-mail correspondence between SterRx personnel and complainants, but without a formal final response. For example:

1. Product complaint PC-2019-011, concerning a hair found on the outside of a pouch of 20 mg phenylephrine in 0.9% sodium chloride (lot (b) (4), manufactured (b) (4)), contains the following text in an e-mail from the supervising pharmacist to the complainant: "Our sterile phenylephrine IV product is filled and sealed within a sterile ISO5 (b) (4) system. The sealed bottle is then labeled and packaged in a clean room."
This lot was produced on blow-fill-seal (BFS) machine (b) (4) in Filling Room (b) (4). The containers were capped in a separate ISO 7 area. The sealed containers were then labeled and packaged (pouched) in an unclassified room.
2. Complaint record PC-2020-135, regarding broken IV bags of 150 mEq sodium bicarbonate in 5% dextrose (Lot (b) (4), manufactured (b) (4)) includes an e-mail from the supervising pharmacist to the complainant stating that your (b) (4) filling system "fills and seals the sterile container within an ISO5 chamber. This sealed and sterile final product is then inspected, labeled, and placed in the labeled foil pouch in an ISO7 room." This lot was produced on the IV bag filling line ((b) (4) in Filling Room (b) (4) and inspected, labeled, and packaged (pouched) in an unclassified room. The complainant replies to the supervising pharmacist, "This information confirms my understanding of your processes, which was that the package preparation and filling all take place in an ISO5 or better environment and the integrity of the drug was never compromised or in danger of being compromised."

***DATES OF INSPECTION**

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Lori M Newman, Investigator

DATE ISSUED

11/4/2021

Edmund F Mrak
Investigator
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Outsourcing Facility 503B

9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/24/2021(Fri), 9/27/2021(Mon), 9/28/2021(Tue),
9/29/2021(Wed), 9/30/2021(Thu), 10/01/2021(Fri), 10/12/2021(Tue), 10/19/2021(Tue),
10/27/2021(Wed), 11/04/2021(Thu)

Lori M Newman
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Signed By: 2003217756
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EMPLOYEE(S) SIGNATURE
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Edmund F Mrak
Investigator
Signed By: Edmund F. Mrak, Jr -6
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DATE ISSUED
11/4/2021

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."