DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/12/2018-3/5/2018* FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Windsor, CT 06095-1024	Manufacturer

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

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

Specifically,

Your firm does not have stability data to support your 90 day Beyond Use Date (BUD) for Rocuronium Bromide 10mg/ml 5ml syringes. Your firm's contract laboratory was using an inappropriate test method in determining the potency of Rocuronium Bromide by measuring for Bromide rather than the active ingredient Rocuronium. From 11/27/2017 to 01/12/2018, (b) (4) lots of Rocuronium Bromide were manufactured and labeled with a BUD of 90 days based upon the inappropriate test data supplied by your contract laboratory.

Additionally, your firm failed to perform an investigation or risk assessment into the impact of using an invalid potency test method for Rocuronium Bromide 10mg/ml 5ml syringes. The test method employed by your contract laboratory was inappropriately testing for Bromide, and not the potency of the active ingredient Rocuronium. The results from this test were used to support your 90 day Beyond Use Date (BUD). From 11/27/2017 to 01/12/2018, (b) (4) lots of Rocuronium Bromide were manufactured and released for distribution using this BUD of 90 days.

OBSERVATION 2

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jonathan G Matrisciano, Investigator Dien N Nguyen, Investigator	X	3/5/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/12/2018-3/5/2018*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Windsor, CT 06095-1024	Manufacturer

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

Specifically,

A. Your firm's system for qualifying the environmental conditions in all (b)(4) of you (b)(4) ISO 5 (b)(4) Laminar Air Flow Hoods (LAFHs) lacks an assessment of the air flow patterns under dynamic conditions for all (b)(4) LAFHs. A review of your dynamic smoke study videos found your firm failed to conduct dynamic smoke studies for all equipment and component configurations used in each of th (b)(4) LAFHs used by your firm to compound sterile drug products.

B. During the inspection of your firm, the following poor aseptic techniques were observed during sterile drug compounding operations:

1. On 2/12/2018, we observed the compounding technician inappropriately placing items in critical areas causing his hands to block first air supply during production of Labetalol HCl 5mg/ml 5ml syringes Lot#1218000495 in hood (b)(4)
2. On 2/20/2018 we observed the compounding technician touching the syringe's plunger during the production of Hydromorphone 1mg/ml 1ml syringes Lot#1218000556 in hood (b)(4) and
3. On 2/23/2018, we reviewed the video captured on 2/20/2018 by the firm's camera for hood (b)(4) during production of Hydromorphone 1mg/ml 1ml syringes Lot#1218000547. We observed the compounding technician touching the syringes' plungers and blocking first air supply with her hand.

C. On 2/14/2018, we observed heavily soiled tacky mats located in the unclassified area in front of the pre-gowning rooms and the un-bagging room (ISO 8 areas) where products and gowning materials are sanitized prior to entering the adjacent ISO 7 areas.

D. On 02/15/2018, we observed an (b)(4) spray bottle hanging on the railing inside the ISO 5 Laminar

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jonathan G Matrisciano, Investigator Dien N Nguyen, Investigator	X	DATE ISSUED 3/5/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/12/2018-3/5/2018*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY Windsor, CT 06095-1024	TYPE ESTABLISHMENT INSPECTED Manufacturer

Air Flow Hood (b) (4) located in Compounding Room (b) (4) The tip of the bottle was pushing against the plastic light cover inside the hood, which created a gap between the aseptic working environment and the unfiltered air space above the light cover.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm failed to investigate an exceeded non-viable particle count limit for ISO 5 LAFH, Equipment (b) (4) located in Compounding Room (b) (4) On Day 2 of your Environmental Monitoring Performance Qualification for (b) (4) conducted on 11/29/2018, you obtained a test result of (b) (4) (b) (4) testing, which far exceeds the acceptance limit (b) (4) (b) (4)

OBSERVATION 4

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

Specifically,

A. Your firm does not routinely monitor and document the differential pressures between the ISO 7 Compounding Rooms and the ISO 5 LAFHs during aseptic compounding operations.

B. Your firm did not follow the procedure "Environmental and Personnel Monitoring of Classified Areas" SOP LAB-007-W, Revision 9. For example, during the production of Fentanyl 50mcg/ml syringes in Room (b) (4) on 2/15/2018, we observed (b) (4) settling plates placed inside the ISO 5 LAFH in locations that did not provide a meaningful evaluation of the actual condition during aseptic operations.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jonathan G Matrisciano, Investigator Dien N Nguyen, Investigator	X	DATE ISSUED 3/5/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/12/2018-3/5/2018*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY Windsor, CT 06095-1024	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 5

Each lot of components, drug product containers and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,

Your firm does not test drug product containers and closures for sterility and endotoxin levels before releasing them for use, and does not review the Certificate of Analysis (CoAs) for these items to ensure they meet your requirements before producing sterile products. For example, your firm failed to test or to evaluate the COAs for syringes and caps used to manufacture drug products during aseptic compounding operations.

OBSERVATION 6

Records are not kept for the maintenance and inspection of equipment.

Specifically,

Your firm does not perform sterility and endotoxin level testing of disposable equipment before release, and does not review a Certificate of Analysis for these items to ensure they meet your requirements for producing sterile product. For example, (b) (4) used during aseptic compounding operations were received but were not tested nor were their CoAs reviewed before release.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jonathan G Matrisciano, Investigator Dien N Nguyen, Investigator	X	3/5/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/12/2018-3/5/2018*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY Windsor, CT 06095-1024	TYPE ESTABLISHMENT INSPECTED Manufacturer

Your firm failed to qualify the (b) (4) for sanitizing the clean rooms when using sterile (b) (4) received from your vendor Contect. Additionally, your firm did not follow your procedure "Cleaning of Classified Areas" SOP COM-002-W, Revision 3, by failing to document the contact times of the disinfectant used in your cleaning logbooks. For example, your firm did not document the disinfectant contact time in either your (b) (4) cleaning logs.

OBSERVATION 8

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically,

The following deficiencies were noted in Clean Room (b) (4)

A. The top of the doorway between ISO 7 Compounding Room (b) (4) and ISO 7 Ante Room (b) (4) was observed to have chipped and peeling paint.

B. The room sign in the ISO 7 Compounding Room (b) (4) was observed to be detaching from the wall creating a gap.

C. The floor between ISO 7 Compounding Room (b) (4) and ISO 7/8 airlock De-Gown Room (b) (4) was observed to have unknown black material/stains on the floor.

D. The HEPA filters numbe (b) (4) located in ISO 7 Compounding Room (b) (4) were observed on 3/5/2018 to be discolored with unknown yellow stain.

OBSERVATION 9

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jonathan G Matrisciano, Investigator Dien N Nguyen, Investigator	X	DATE ISSUED 3/5/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/12/2018-3/5/2018*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY Windsor, CT 06095-1024	TYPE ESTABLISHMENT INSPECTED Manufacturer

Specifically,

Your firm failed to perform potency testing on each lot of finished drug product prior to release and distribution. Your firm only performs drug product potency testing during each product's initial stability study, which your firm then uses to justify the potency of each subsequent lot of sterile drug product compounded by your firm.

OBSERVATION 10
The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. Your firm failed to follow your label control procedures which ensure the correct information is printed on finished drug product labels prior to release and distribution. For example, Labetalol HCl 5mg/ml 4ml syringes, Lot #1217000213, was incorrectly labeled with a compounding date of 12/27/2018 and a 90-day BUD of 3/27/2019, where the correct compounding date was 12/27/2017 and BUD was 3/27/2018. The QCU released and distributed Labetalol HCl 5mg/ml 4ml syringes, Lot #1217000213, with the incorrect compounding and BUD dates.

B. On 2/13/2018, we observed Form LG-024-W "Packaging Line Clearance Log" for inspection line number 2 and 8 were missing the verifier's initials and dates. Documentation of the verifier's initials and date indicates a second individual confirmed packaging line clearance was performed correctly, which is a critical step to prevent product and labeling mix ups.

OBSERVATION 11
Established test procedures are not followed.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jonathan G Matrisciano, Investigator Dien N Nguyen, Investigator	X	3/5/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	2/12/2018-3/5/2018*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Milton Boyer, CEO

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY Windsor, CT 06095-1024	TYPE ESTABLISHMENT INSPECTED Manufacturer

On 2/23/2018, we observed an inspector on line (b) (4) performing finished product visual inspection of Hydromorphone 1mg/ml syringes, Lot #1218000541. We observed the inspector shaking the syringes (b) (4) during his inspection, instead of (b) (4) the syringes as required by the firm's visual inspection procedure.

***DATES OF INSPECTION**
2/12/2018(Mon), 2/13/2018(Tue), 2/14/2018(Wed), 2/15/2018(Thu), 2/16/2018(Fri), 2/20/2018(Tue), 2/21/2018(Wed), 2/22/2018(Thu), 2/23/2018(Fri), 3/05/2018(Mon)

X Jonathan G Matrisciano
Investigator
Signed By: Jonathan G Matrisciano -S
Date Signed: 03-05-2018 14:44:38

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jonathan G Matrisciano, Investigator Dien N Nguyen, Investigator X Dien N Nguyen Investigator Signed By: 2001238155 Date Signed: 03-05-2018 14:41:46	3/5/2018