

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

**DISTRICT ADDRESS AND PHONE NUMBER**

4040 North Central Expressway, Suite 300  
Dallas, TX 75204  
(214)253-5200 Fax: (214)253-5314

**DATE(S) OF INSPECTION**

9/25/2017-9/29/2017

**FEI NUMBER**

3010683157

**NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED**

James M. Boyer, Chief Executive Officer

**FIRM NAME**

SCA Pharmaceuticals, LLC

**STREET ADDRESS**

8821 Knoedl Ct

**CITY, STATE, ZIP CODE, COUNTRY**

Little Rock, AR 72205-4600

**TYPE ESTABLISHMENT INSPECTED**

Outsourcing Facility

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 the system for monitoring environmental conditions.

Specifically,

- a) You failed to demonstrate control of your environment by exceeding action levels in the laminar flow hoods environment (ISO 5) located in rooms (b) (4) (ISO 7) and (b) (4) (ISO 7).

Since January 2017, you have had 22 action levels in the ISO 5 environment of which 7 are air samples as seen in the chart below.

**Room (b) (4) LFHs**

Date	Sample Location	Organism
1/14/2017	(b) (4) 1CFU 14Jan17	<i>Aeromicrobium fastidisoum</i>
3/7/2017	(b) (4) 1CFU-07Mar17	<i>Staphylococcus epidermidis</i>
6/16/2017	(b) (4) 1CFU-16JUN17	<i>Cladosporium halotolerans</i>
3/14/2017	(b) (4) CFU-14MAR17	<i>Paenibacillus urinalis</i>
	(b) (4) -4CFU (b) (4) -4CFU (b) (4) (b) (4) -3CFU	<i>Bacillus nealsonii, Bacillus subtilis, Bacillus niacini, Bacillus jeogali</i>

**SEE REVERSE  
OF THIS PAGE**

**EMPLOYEE(S) SIGNATURE**

Nimmy Mathews, Investigator  
Claire M Minden, Investigator

Claire M Minden  
Investigator  
Signed By: Claire M. Minden -S  
Date Signed: 09-29-2017 13:40:13

X

**DATE ISSUED**

9/29/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION																																																									
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<p>Since January 2017, you have had 30 action levels in the ISO 5 environment of which 11 are air samples as seen in the chart below.</p> <p><b>Room (b) (4) LFHs</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Date</th> <th style="width: 35%;">Sample Location</th> <th style="width: 50%;">Organism</th> </tr> </thead> <tbody> <tr> <td>7/14/2017</td> <td>(b) (4) -1CFU-14JUL17</td> <td><i>Oceanobacillus kimchii</i></td> </tr> </tbody> </table>				Date	Sample Location	Organism	7/14/2017	(b) (4) -1CFU-14JUL17	<i>Oceanobacillus kimchii</i>																																																
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1/13/2017	(b) (4)	-1CFU 13Jan17	<i>Microbacterium phyllosphaerae</i>
7/6/2017	(b) (4)	-1CFU-06JUL17	<i>Micrococcus luteus</i>
3/4/2017	(b) (4)	1CFU-04Mar17	<i>Chaetomium globosum</i>
4/5/2017		1CFU-05APR17	<i>Psychrobacillus psychrodurans</i>
7/8/2017		1CFU-08JUL17	<i>Micrococcus luteus</i>
8/15/2017		1CFU-15AUG17	<i>Micrococcus luteus</i>
3/20/2017		1CFU-20MAR17	<i>Massilia sp</i>
4/19/2017		1CFU-19APR17	<i>Penicillium corylophilum</i>
3/15/2017	(b) (4)	1CFU-15MAR17	<i>Aspergillus sp</i>
6/21/2017		4CFU-21JUN17	<i>Bacillus spp</i>
9/1/2017		4CFU-01Sep17	<i>Staphylococcus epidermidis, Staphylococcus capitis</i>
2/15/2017	(b) (4)	1CFU-15Feb17	<i>Streptomyces althioticus</i>
1/19/2017		1CFU (b) (4) 19Jan17	<i>Planomicrobium okeanoikoites</i>
8/8/2017	(b) (4)	1CFU-08AUG17	<i>Aspergillus glaucis/niveoglaucus/pseudoglaucus/ruber</i>
7/26/2017		1CFU-26JUL17	<i>Cladosporium tenuissimum</i>
1/13/2017		5CFU 13Jan17	<i>Bacillus thuringiensis</i>
6/23/2017	(b) (4)	1CFU 23JUN17	<i>Penicillium corylophilum</i>
5/23/2017	(b) (4)	1CFU-23MAY17	<i>Aspergillus amstelodami / cristatus</i>
5/24/2017	(b) (4)	3CFU-24MAY17	<i>Bacillus circulans, Lysinibacillus massiliensis</i>
8/28/2017	(b) (4)	1CFU-28AUG17	<i>Penicillium aurantiacum</i>
2/1/2017	(b) (4)	1CFU 01Feb17	<i>Penicillium chrysogenum / flavigenum</i>
9/5/2017	(b) (4)	2CFU-05Sep17	<i>Cladosporium sp., Bacillus licheniformis</i>
9/6/2017	(b) (4)	5CFU-06Sep17	<i>Pithomyces sacchari, Micrococcus luteus, Staphylococcus capitis</i>

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

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Claire M Minden, Investigator

Claire M Minden  
Investigator  
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<p>b) The HEPA filter (b) (4) adjacent to the door in room (b) (4) (classified as ISO 7) has not been leak tested since September 2015.</p>																											
<p><b>OBSERVATION 2</b></p> <p>There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.</p> <p>Specifically, you continued to release product when you met or exceeded your action limit.</p>																											
<p><b>OBSERVATION 3</b></p> <p>Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.</p> <p>Specifically, on September 25, 2017 we observed one individual with exposed skin of the neck between the mask and hood during aseptic operations in the cleanroom.</p>																											
<p><b>OBSERVATION 4</b></p> <p>Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.</p>																											
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<p>Specifically, certification of the ISO 7 and ISO 5 environment does not occur under dynamic conditions.</p>						
<p><b>OBSERVATION 5</b>            Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.</p> <p>Specifically, on September 26, 2017, the wheels of carts and chairs were not cleaned during our observation of the cleaning process in cleanroom (b) (4) (ISO 7) classified environment.</p> <p>In addition, we observed the following:</p> <ul style="list-style-type: none"> <li>• Employees did not always clean back to front, left to right.</li> <li>• Gowns of employees touched previous cleaned areas of equipment.</li> <li>• Employees did not always change wipes after each wipe.</li> </ul>						
<p><b>OBSERVATION 6</b>            The labels of your outsourcing facility's drug products are deficient.</p> <p>Specifically, the labels of some of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A).</p> <ul style="list-style-type: none"> <li>• The dosage form is not on your drug product labels. Examples of labels that do not contain the required information include:               <ul style="list-style-type: none"> <li>○ Ketamine 50 mg/5 mL in 0.9% Sodium Chloride Single Dose Syringe</li> <li>○ Ropivacaine 0.2% in 0.9% Sodium Chloride Single Dose CADD Cassette</li> <li>○ Norepinephrine 16 mg in 0.9% Sodium Chloride 250 mL Bag</li> <li>○ Rocuronium 50 mg/5mL Single Dose Syringe</li> </ul> </li> <li>• The statement, "This is a compounded drug" is not on some of your drug product labels. Examples of labels that do not contain the required information include:               <ul style="list-style-type: none"> <li>○ Lidocaine PF 100 mg/5mL Single Dose Syringe</li> </ul> </li> </ul>						
<b>SEE REVERSE OF THIS PAGE</b>		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small>            Nimmy Mathews, Investigator            Claire M Minden, Investigator         </td> <td style="width: 40%; vertical-align: top; text-align: center;"> <small>DATE ISSUED</small>            9/29/2017   <small>Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 09/29/2017 13:40:13</small>  <div style="text-align: left; margin-top: 5px;">X</div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Nimmy Mathews, Investigator Claire M Minden, Investigator	<small>DATE ISSUED</small> 9/29/2017  <small>Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 09/29/2017 13:40:13</small> <div style="text-align: left; margin-top: 5px;">X</div>	
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<table border="0" style="width: 100%;"> <tr> <td style="width: 33%; text-align: left;">FORM FDA 483 (09/08)</td> <td style="width: 33%; text-align: center;">PREVIOUS EDITIONS OBSOLETE</td> <td style="width: 33%; text-align: center;"><b>INSPECTIONAL OBSERVATIONS</b></td> </tr> </table>				FORM FDA 483 (09/08)	PREVIOUS EDITIONS OBSOLETE	<b>INSPECTIONAL OBSERVATIONS</b>
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 9/25/2017-9/29/2017 FEI NUMBER 3010683157	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED James M. Boyer, Chief Executive Officer			
FIRM NAME SCA Pharmaceuticals, LLC		STREET ADDRESS 8821 Knoedl Ct	
CITY, STATE, ZIP CODE, COUNTRY Little Rock, AR 72205-4600		TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<ul style="list-style-type: none"> <li>○ Ephedrine 50 mg/10mL in 0.9% Sodium Chloride Single Dose Syringe</li> <li>○ Atropine 1.2 mg/3 mL Single Dose Syringe</li> <li>• The statement, "Office Use Only" is not on some of your drug product labels. Examples of labels that do not contain the required information include: <ul style="list-style-type: none"> <li>○ Lidocaine PF 100 mg/5mL Single Dose Syringe</li> <li>○ Ephedrine 50 mg/10mL in 0.9% Sodium Chloride Single Dose Syringe</li> <li>○ Atropine 1.2 mg/3 mL Single Dose Syringe</li> </ul> </li> <li>• A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient is not on your drug product labels. Examples of labels that do not contain the required information include: <ul style="list-style-type: none"> <li>○ Norepinephrine 16 mg in 0.9% Sodium Chloride 250 mL Bag</li> <li>○ Oxytocin, 30 units in 0.9% Sodium Chloride 500 mL Bag</li> <li>○ Ephedrine 50 mg/10mL in 0.9% Sodium Chloride Single Dose Syringe.</li> </ul> </li> </ul>			
<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 30%;"> <p>X Nimmy Mathews Investigator Signed By 2000790204 Date Signed 09-29-2017 13:41:04</p> </div> <div style="width: 65%;"></div> </div>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nimmy Mathews, Investigator Claire M Minden, Investigator		<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 30%;"> <p>X Claire M Minden Investigator Signed By Claire M Minden IS Date Signed 09-29-2017 13:40:12</p> </div> <div style="width: 65%;"></div> </div>
FORM FDA 483 (09/08)		PREVIOUS EDITIONS OBSOLETE	PAGE 6 OF 6 PAGES