DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314 ORAPharm2_responses@fda.hhs.gov	10/28/2019-11/7/2019* FEI NUMBER 3010683157

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: James M. Boyer, Chief Executive Officer

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, Inc.	8821 Knoedl Ct.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Little Rock, AR 72205-4600	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 MPLEMENT 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:

OBSERVATION 1

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your method allows for (b) (4) with the (b) (4) for sterility testing which is not equivalent to USP <71>.

OBSERVATION 2

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, on April 5, 2019, you were notified of a confirmed potency failure for Vasopressin 0.4 units/ml in 0.9% NaCl (b) (4) ml bag at the 50-day timepoint for beyond use dating (BUD) by your contract testing laboratory. You assigned a 90-day BUD until May 7, 2019 when you changed the BUD to 50 days. You did not notify your customers of the change in date for (b) (4) lots of product you distributed prior to changing the BUD due to sub-potency results.

In addition, your complaint procedure does not specifically include directions when a reserve/retain sample will be tested or visually inspected as part of the complaint investigation as evidenced by CUS 19-020-LR, CUS 19-058-LR, CUS 10-059-LR, CUS 19-060-LR, CUS 19-069-LR, CUS 19-079-LR, and CUS 19-094-LR.

OBSERVATION 3

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Claire M. Minden Digitally signed by Claire M. Minden -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300178102, cn=Claire M. Minden -S Date: 2019.11.07 11:05:05 -06'00'	Claire M. Minden, Investigator	11/07/2019

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Specifically, you have never conducted an audit trail review of the SCAN RDI system since you began using it in 2013 for sterility analysis nor do you have a procedure for conducting an audit trail review. Additionally, an employee who performs most of the scanning for the sterility analysis signs in with her Administrator access to perform the scans.

OBSERVATION 4

The results of the examination of the packaged and labeled products were not documented in the batch production or control records.

Specifically, I observed during the visual inspection by employees rejects from the 100% and the AQL were placed in the same bin, thus not allowing for accurate data to be entered in the batch records to determine if both passed your specification for visual inspection as defined in SOP COM-013-LR. For the AQL, critical defect limit is (b) (4) so if both rejects were counted as part of the 100% inspection, the lot would pass instead of failing.

OBSERVATION 5

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, you compound drug products that:
a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
b) are not identical or nearly identical to an approved drug but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

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	CMM	Claire M. Minden, Investigator	11/07/2019

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Examples of compounded drug products that are essentially a copy of one or more approved drugs include;
- Succinylcholine 20 mg/ml injection
- Glycopyrrolate 0.2 mg/ml injection
- Fentanyl 50 mcg/ml injection and
- Phenylephrine 0.2 mg/ml, and 0.8 mg/ml injection.

OBSERVATION 6

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically, employees responsible for the sterility analysis by Scan RDI are two months late in their (b) (4) recertification and continue to process sterility analysis using Scan RDI.

*DATES OF INSPECTION
10/28/2019(Mon), 10/29/2019(Tue), 10/30/2019(Wed), 10/31/2019(Thu), 11/01/2019(Fri), 11/04/2019(Mon), 11/06/2019(Wed), 11/07/2019(Thu)

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