

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

DISTRICT ADDRESS AND PHONE NUMBER
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
(973) 331-4900 Fax: (973) 331-4969

DATE(S) OF INSPECTION
4/18/2016-6/28/2016*
FEI NUMBER
3012292690

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hank Incognito, Owner

FIRM NAME
Sewaren Innovative Pharmaceutical
Packaging dba SIPP

STREET ADDRESS
994 Rahway Ave Ste 1

CITY, STATE, ZIP CODE, COUNTRY
Avenel, NJ 07001-1946

TYPE ESTABLISHMENT INSPECTED
Producer of Sterile Drugs

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

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, there is a lack of potency and sterility assurance for preserved sterile medroxyprogesterone acetate (MPA) preparations in that beyond use dates, up to 13 months, are assigned without stability data utilizing equipment, materials and procedures that are current. Between 11/11/2015 and 02/03/2016, approximately 6% batches of MPA were produced and distributed by your firm.

OBSERVATION 2

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

Specifically, (b) (4) vials of medroxyprogesterone acetate (MPA) 150mg/mL, lot G1510, were released by your firm for distribution on 07/29/2015, two days prior to obtaining satisfactory test results from your contract laboratory. The laboratory released the results of lot G1510 on 07/31/2015.

In addition, there is no data to support the number of units tested for potency, endotoxin and sterility as the number of units is not representative of the batch size. The tested units represented (b) (4) of each batch. The following table provides examples of MPA lots where (b) (4) was tested by your contract laboratory:

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Zakaria I Ganiyu, Investigator
Nancy F Scheraga, Investigator
Melissa T Roy, Investigator

6/18/2016
 Zakaria I Ganiyu
Zakaria I Ganiyu
Investigator
Signed by: Zakaria I Ganiyu (S)

DATE ISSUED
6/28/2016

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Lot #	Date Compounded	Batch Size (in mL)	Qty Sent to Lab (b) (4)	Total Qty Tested by Lab
G1510	07/10/2015	(b) (4)	(b) (4)	(b) (4)
K1511	11/11/2015			
L1523	12/23/2015			
A1606	01/06/2016			
A1629	01/29/2016			
B1603	02/03/2016			

OBSERVATION 3

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

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

Specifically, media fill simulations are not representative of the actual production of aseptically filled sterile products. For example, the production of medroxyprogesterone acetate involves (b) (4)

(b) (4) in the (b) (4). However, the media fill simulation performed on (b) (4) was limited to (b) (4) (b) (4). The media fill simulation was not representative of the worst case scenario due to the use of a (b) (4), an inadequate number of (b) (4) filled and the lack of equivalent aseptic manipulations through finished (b) (4) (b) (4) that typically occurs.

SEE REVERSE OF THIS PAGE

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Nancy F Scheraga, Investigator
Melissa T Roy, Investigator

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6/28/2016

X Zakaria I Ganiyu
Zakaria I Ganiyu
Investigator
Signed by Zakaria I Ganiyu

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***DATES OF INSPECTION**
4/18/2016(Mon), 5/12/2016(Thu), 5/20/2016(Fri), 6/28/2016(Tue)
6/28/2016 6/28/2016

<input checked="" type="checkbox"/> Nancy F Scheraga	<input checked="" type="checkbox"/> Melissa T Roy
<small>Nancy F Scheraga Investigator Signed by: Nancy Scheraga -S</small>	<small>Melissa T Roy Investigator Signed by: Melissa T. Roy -S</small>

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zakaria I Ganiyu, Investigator Nancy F Scheraga, Investigator Melissa T Roy, Investigator	DATE ISSUED 6/28/2016
		<input checked="" type="checkbox"/> Zakaria I Ganiyu <small>Zakaria I Ganiyu Investigator Signed by: Zakaria I Ganiyu -S</small>