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 11 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, 150 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) (d) of each batch. The following table provides examples of MPA lots where (b) (d) was tested by your contract laboratory:
OBSERVATION 3

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 media fill simulation. However, the media fill simulation performed on was limited to an inadequate number of filled and the lack of equivalent aseptic manipulations through finished that typically occurs.
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE OF INSPECTION
4/18/2016-6/28/2016*

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

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

Nancy F. Scheraga
Investigator
Signed by: Nancy Scheraga -S

Melissa T. Roy
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