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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 550 W Jackson Blvd Suite 1500<br>Chicago, IL 60661<br>312-353-5863<br>Email Responses To: ORAPHARM3_RESPONSES@fda.hhs.gov<br>Attn: Program Division Director | 07/17, 07/18, 07/20, 7/25/18<br>FEI NUMBER<br>3013468333 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Thomas Cappetta, Vice President of Pharmacy Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Orsini Pharmaceutical Services, Inc. dba Orsini Healthcare | 1111 Nicholas and 1107 Nicholas Blvd. |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Elk Grove Village, IL 60001 | Producer of Sterile Drugs |

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE NSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERM NATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARD NG 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) DUR NG THE INSPECTION OR SUBMIT THIS NFORMATION TO FDA AT THE ADDRESS ABOVE. F YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN NSPECTION OF YOUR FIRM WE OBSERVED:

## OBSERVATION 1

Cleaning procedures for the ISO-5 LAF cabinets and the classified areas where sterile drug products are produced (such as the (b) (4) each containing (b) (4) produced on 07/17/18) are deficient in that:

a. The firm is not using a sporicidal agent to sanitize the classified areas including the ISO-5 laminar airflow (LAF) cabinets and ISO-5 IV Room.
b. The disinfectants currently used to sanitize the ISO-5 LAF cabinets and ISO-5 IV Room ((b) (4) (b) (4) are not labeled as sterile.
c. The process for sanitization prior to compounding does not require that the compounding personnel sanitize the interior walls of the ISO-5 LAF cabinet prior to compounding.
d. The lint free wipes used to sanitize the benchtop were not labeled as sterile. The lint free wipes are used in conjunction with (b) (4) (labeled sterile) to disinfect the ISO-5 LAF cabinet bench top and exterior of equipment used in compounding sterile drugs.

## OBSERVATION 2

You produced beta-lactam drugs without providing adequate containment and segregation to prevent cross-contamination. Specifically, multiple sterile β-lactam drugs are produced in the same positive pressure ISO-5 area that are used to produce other sterile non β-lactam sterile drugs, and there is no procedure to specify how spills are to be cleaned.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE *(Print or Type)* | DATE ISSUED |
|---|---|---|---|
| | Brian Nicholson -S Digitally signed by Brian Nicholson -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300192161, cn=Brian Nicholson -S Date: 2018.07.25 09:15:15 -05'00' | Brian D. Nicholson, C.S.O. | 07/25/2018 |