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

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 250 Marquette Ave, Ste 600<br>Minneapolis, MN 55401<br>(612) 334-4100 Fax: (612) 334-4134<br><br>Industry Information: www.fda.gov/oc/industry | 07/23, 24, 26, 30/2018 |
| | FEI NUMBER<br>3012360920 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Stephen G. Anderson, Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| W & C Apothecary dba The Apothecary | 165 19th St S, Ste 102 |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Sartell, MN 56377-2567 | Producer of non-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 (I) (WE) OBSERVED:

## OBSERVATION 1

You produced beta-lactam drugs and highly potent drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

a. Your firm produced the following batches of ceftazidime:

Batch 03201710@12 on 10/04/2017, using (b) (4) hood #1
Batch 23201801@11 on 01/23/2018, using (b) (4) hood #2
Batch 15201805@20 on 05/16/2018, using (b) (4) hood #1

Ceftazidime powder was mixed with other powder excipients and encapsulated. These batches were produced without adequate inactivation of the drug in the work area and on equipment used. Batch records for 03201710@12 and 15201805@20 indicate that (b) (4) and (b) (4) were used during cleaning, while the batch record for 23201801@11 indicates that only (b) (4) was used during cleaning. Pharmacist-In-Charge (b) (6) stated to me that the batches were made with equipment dedicated to non-hazardous drug products and thus cleaning would have been performed with only (b) (4) (b) (6) stated that the batch records indicating that (b) (4) was used during cleaning were inaccurate.

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (*Print or Type*) | DATE ISSUED |
|---|---|---|---|
| | Charles L. Zhou -S | Charles L. Zhou, Investigator | 07/30/2018 |

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All products are made in these (b) (4) hoods, and any products made after these ceftazidime batches may be at risk of cephalosporin cross-contamination. For example:
-Batch 16201817@11, duloxetine/oil 15 mg/ml suspension, was produced on 05/24/2018 in (b) (4) hood #1.
-Batch 05201806@16, progesterone 275 mg capsule, was produced on 06/05/2018 in (b) (4) hood #2.

b. On 07/26/2018, I observed the production of batch 23201807@22, progesterone/testosterone 50/1 mg troche in (b) (4) hood #1. After production of this batch, pharmacy tech (b) (6) applied (b) (4) (b) (4) solution to the hood, immediately wiped it up, therefore not leaving the (b) (4) for a (b) (4) minute contact time, and applied (b) (4) and allowed that to sit. Batch 26201807@11, testosterone ATR 100 mg/g gel, was the next batch produced after batch 23201807@22.

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