DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically, on September 10, 2018 we observed your daily cleaning of ISO 5 aseptic processing area was done without the use of any sporicidal agents. We noted that during the cleaning process, *(b) (4)* was the only agent used. We also noted that there is no sporicidal agent used in the *(b) (4)* cleaning of the ISO 5 aseptic processing area. Your firm stated no sporicidal agent is used in the ISO 5 aseptic processing area.

OBSERVATION 2

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, On September 10, 2018, we observed an employee clean the ISO 5 aseptic processing area with *(b) (4)* and non-sterile wipes before starting aseptic processing of Cefazolin 2gm/100ml Prescription # *(b) (6)*.

OBSERVATION 3

Equipment was and Materials or supplies were not disinfected prior to entering the aseptic processing areas.
Specifically, Items are sprayed with (b) (4) in the non-classified area of the pharmacy, then transported to the non-classified (b) (4) which leads directly to the ISO 7 buffer area. These items are then placed into the ISO 5 aseptic processing area without further disinfection.

**OBSERVATION 4**
The ISO 5 classified aseptic processing areas had difficult to clean equipment or surface.

Specifically, The back of the ISO-5 aseptic processing area does not have a smooth cleanable surface and it contains (b) (4) which include (b) (4) type surfaces.

**OBSERVATION 5**
ISO 5 classified areas were not certified under dynamic conditions.

Specifically,

Smoke studies performed in the ISO 5 laminar hood were not performed under dynamic conditions that represent your aseptic processing practices. We observed the aseptic processing of Cefazolin 2gm/100ml Prescription # (b) (6) which included (b) (4) in the ISO 5 hood, using a repeater pump with (b) (4) which were not replicated during the smoke studies. There is no video or description provided of the smoke study and no employees of your firm participated or witnessed the smoke study.
OBSERVATION 6

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, Your firm follows the instructions of the \( (b) (4) \) media fill kit for risk level-1 (simple procedure) which involved \( (b) (4) \) contained in the kit and an \( (b) (4) \) provided by your firm. We observed the aseptic processing of Cefazolin 2gm/100ml Prescription # \( (b) (6) \) which included \( (b) (4) \) in the ISO 5 hood, using a repeater pump with \( (b) (4) \) The \( (b) (4) \) media fill kit risk level 1 procedure does not simulate the batch size or use of repeater pump and \( (b) (4) \) which are part of your firm’s routine conditions.

*DATES OF INSPECTION
9/10/2018(Mon), 9/11/2018(Tue), 9/12/2018(Wed), 9/20/2018(Thu), 9/21/2018(Fri)
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE(S) OF INSPECTION
9/10/2018-9/21/2018*

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bradley M. Phillips, Director of LTC Pharmacy Ops.

FIRM NAME
Thrifty White Drug #762

CITY, STATE, ZIP CODE, COUNTRY
Minneapolis, MN 55442-1675

TYPE ESTABLISHMENT Inspected
Producer of Sterile and Non-sterile Drug Products

SEE REVERSE OF THIS PAGE
Anthony J Ladner, Investigator
Ross J Grigsby, Investigator

DATE ISSUED
9/21/2018