

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

|   |  |
|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER<br>6th & Kipling St. (P.O. Box 25087)<br>Denver, CO 80225-0087<br>(303)236-3000 Fax:(303)236-3100 | DATE(S) OF INSPECTION<br>6/5/2017-6/12/2017* |
|   | FEI NUMBER<br>3013544438                     |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Ms. Karen L. Muir , Pharmacist in Charge (PIC)

|   |   |
|---|---|
| FIRM NAME<br>Safeway, Inc.                                | STREET ADDRESS<br>6100 Hellyer Ave, Suite 100                             |
| CITY, STATE, ZIP CODE, COUNTRY<br>San Jose, CA 95138-1057 | TYPE ESTABLISHMENT INSPECTED<br>Producer of Non-sterile and 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**

Aseptic processing areas are deficient in that walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

On 6/7/17, during inspectional tour of the ISO 7 Cleanroom area, I observed the following difficult to clean surface areas within the ISO 5 area of the (b) (4) Laminar Flow Hood:

- A. Two cracks, approximately 2 inches in length, were found in the left and right plexiglass side panels inside the ISO 5 area. Each crack was found on both the left and right side panels, near the rear middle edge of the paneling, where side paneling attaches to the rear panel.
- B. Two, approximately two feet in length, exposed fluorescent light bulbs and electrical wiring units, were found in both the right and left upper corners of the laminar flow hood. The lighting units were designed to be covered; however, the two covers were missing.

**\*DATES OF INSPECTION**

6/05/2017(Mon),6/06/2017(Tue),6/07/2017(Wed),6/08/2017(Thu),6/09/2017(Fri),6/12/2017(Mon)

|                                 |  |   |                          |
|---------------------------------|--|---|--------------------------|
| <b>SEE REVERSE OF THIS PAGE</b> | EMPLOYEE(S) SIGNATURE<br>Zachery L Miller, Investigator<br>Haroon Vohra, Investigator<br><i>Haroon Vohra</i> | 6/12/2017   | DATE ISSUED<br>6/12/2017 |
|                                 |  | <input checked="" type="checkbox"/> Zachery L Miller<br><small>Zachery L Miller<br/>Investigator<br/>Signed by: Zachery L Miller -5</small> |                          |