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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 09/03/2015 - 09/18/2015*<br>FEI NUMBER<br>3006365166 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Darrell W. Cavalari, Pharmacist In Charge

| FIRM NAME | STREET ADDRESS |
|---|---|
| Grandpa's Compounding Pharmacy, Inc. | 7563 Green Valley Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Placerville, CA 95667-3917 | 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 WE OBSERVED:**

## OBSERVATION 1

Failure to reject any lot of components that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically, your firm's Pharmacist In Charge (PIC) stated the Domperidone powder supplier was (b) (4) Your firm received (b) (4) of Domperidone lot (b) (4) in May 2014 and another (b) (4) of the same lot in February 2015. The product label of Domperidone lot (b) (4) states "NOT FOR HUMAN USE". Your firm did not reject lot #(b) (4) of Domperidone and instead used the lot to produce Domperidone capsules for human use. From approximately May 2014 until April 16, 2015, your firm dispensed (b) (4) prescriptions of Domperidone drug products for human use produced with Domperidone powder, lot (b) (4). Prescriptions dispensed included quantities such as 45, 60, 90, 180, and 540 capsules.

The (b) (4) prescriptions produced between May 2014 and April 16, 2015 consisted of the following dosage forms and strengths of Domperidone for human use:
- 5mg Blue Capsules
- 10mg Capsules
- 20mg Capsules

## OBSERVATION 2

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, your firm failed to follow SOP No. 9.2.10 entitled, "Complaint and Mishap Rectification". The SOP states "Record on the Complaint Form and file all reported complaints or mishaps regarding compounding and formulations or regarding the operation of the pharmacy (eg, drug incompatibility, contamination, compounding errors or omissions, etc.)." We asked the PIC how complaints are handled and where the complaint and subsequent investigation is documented. The PIC stated complaints are handled on a (b) (4) and some complaints are (b) (4) (b) (4) and (b) (4). However, the PIC also stated that unless a complaint can be confirmed it would not be documented as a complaint and any complaint investigation also would not be documented.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Ashar P. Parikh, Investigator<br>Anh Lac, Investigator | 09/18/2015 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 09/03/2015 - 09/18/2015*<br>FEI NUMBER<br>3006365166 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Darrell W. Cavalari, Pharmacist In Charge

| FIRM NAME | STREET ADDRESS |
|---|---|
| Grandpa's Compounding Pharmacy, Inc. | 7563 Green Valley Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Placerville, CA 95667-3917 | Producer of Non-Sterile Drugs |

For example, your PIC stated a complaint letter was received from a patient around May 2015 for potential contamination of progesterone lozenges. Ten out of thirty lozenges were returned with the letter from the patient. Your firm's PIC stated the pharmacy investigated the complaint (b) (4) to determine if there was contamination of the drug product. He stated the investigation revealed the contamination could not be confirmed however, neither the complaint nor the investigation was documented. In addition, your PIC stated your firm did not contact the patient to obtain additional information regarding the potential contamination. Your PIC was unable to locate and provide the complainant's letter during the inspection.

*** DATES OF INSPECTION:**
09/03/2015(Thu), 09/08/2015(Tue), 09/18/2015(Fri)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Ashar P. Parikh, Investigator<br>Anh Lac, Investigator | 09/18/2015 |