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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 3/20/2017-3/28/2017* |
| | FEI NUMBER<br>3009248035 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Samuel D. Raoof , CEO/President

| FIRM NAME | STREET ADDRESS |
|---|---|
| TSDR Pharmacy Inc. dba brandMD Skin Care | 20660 Nordhoff St Unit C |
| CITY, STATE, ZIP CODE, COUNTRY<br>Chatsworth, CA 91311-6114 | TYPE ESTABLISHMENT INSPECTED<br>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 OBSERVED:**

**OBSERVATION 1**

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, drug product containers, closures and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, there are no specifications and test procedures established for some of the critical attributes associated with your firm's drug products prepared in the pharmacy room (b) (4). For example,

A. There is no specification for assay on any of the drug products prepared in your pharmacy room.
B. There are no test procedures established for the Color, Odor, Appearance, pH, and Viscosity tests used for the prepared drug product release.
C. The homogeneity of your prepared bulk drug products was not demonstrated.

**OBSERVATION 2**

There is no quality control unit.

Specifically, your firm does not have a quality control unit that has the responsibility and authority to approve or reject all components, drug product container/closures, packaging materials, labeling, and drug product. For example,

A. Your firm's SOP No. A-07, Compounding Quality Assurance, Rev.00, Effective August 1, 2016 defines the responsibility of Compounding Quality Assurance; however, your firm does not have a quality control unit or a designated person who carries quality control unit responsibility.
B. The SOP No. A-07 states that the pharmacy's (b) (4) includes (b) (4) " No such procedures were available and no quantitative analyses on the potency of prepared drug products were ever carried out to support the drug product label claims.
C. Your Pharmacist-in-Charge (PIC) is responsible to perform all drug preparation activities, including but not limited to (b) (4) . None of these activities were reviewed and verified by a second person.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Liming Zhang, Investigator | 3/28/2017<br>X Liming Zhang<br>Liming Zhang<br>Investigator<br>Signed by: Liming Zhang -S | 3/28/2017 |

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D. While your PIC carries out all the drug product preparation works, the completed Formulation and Batch Compounding Records (FBCR) were approved by the PIC himself. The FBCRs were not reviewed and approved by a quality person other than the PIC.

E. Your firm purchased the following three active pharmaceutical ingredients (API) for the drug products prepared in your pharmacy room. However, the APIs are received without specific identification test conducted by your quality control unit.

- (b) (4) Hydrocortisone
- Hydroquinone
- Retinoic Acid/Tretinoin

In addition, the identification tests were not performed on any of the received excipients used in the preparation of drug products.

**OBSERVATION 3**

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established and written.

Specifically, your firm's prepared drug products do not include specification for microorganisms and were never tested for microorganisms. The efficacy of the preservatives contained in your drug products has not been demonstrated at the end of product beyond use date.

**OBSERVATION 4**

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm's cleaning practice for drug product preparation equipment and pharmacy room is not adequate in that,

A. There are no cleaning procedures established that provide specific cleaning instructions for (b) (4) (b) (4) (b) (4), S/N (b) (4), (b) (4) S/N (b) (4), and utensils that are used for all your drug product preparations.

B. Your firm uses (b) (4) as the final rinse for the (b) (4), dissembled equipment parts, and utensils before applying (b) (4) to sanitize the equipment or parts. The quality of (b) (4) was never assessed.

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C. There are no cleaning and usage logs for equipment used in the drug product preparation. There is no cleaning log for pharmacy room cleaning.

D. On 21Mar2017, a strip of black oily residue was observed inside the (b) (4) of the (b) (4). According to the PIC, the (b) (4) had been cleaned already. Your firm's CEO was able to wipe out that black residue with his fingers.

**OBSERVATION 5**

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, the Master Formulation and Batch Compounding Records for your drug products lack essential details and instructions to ensure that the prepared drug products have the quality and potency claimed on the product labels. For example,

E. The mixing speed and mixing time for the bulk drug product preparation are not defined. The mixing speed and mixing time were never recorded on the executed formulation and batch compounding records.

F. There is no in-process testing required to ensure proper mixing of the ingredients to achieve bulk drug product uniformity.

**OBSERVATION 6**

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and of adequate size to facilitate operations for its intended use and cleaning and maintenance.

Specifically, your firm's equipment that are used for your drug product preparation are not adequate for its intended purpose. For example,

G. The balance (b) (4) S/N (b) (4) used for ingredient weighing was never verified on the day of use. The weight measurements for some of the ingredients were outside the calibrated range.

H. The (b) (4) ((b) (4) S/N (b) (4)) used for (b) (4) test on the prepared drug products were not verified with (b) (4) standards on the day of use.

***DATES OF INSPECTION**

3/20/2017(Mon),3/21/2017(Tue),3/22/2017(Wed),3/28/2017(Tue)

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| | Liming Zhang, Investigator<br>X Liming Zhang<br>Liming Zhang<br>Investigator<br>Signed by: Liming Zhang -5 | 3/28/2017 |