DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION40
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	03/20/2017-03/29/2017
	FEI NUMBER 3004497213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. John J. Carson, R.Ph., Chief of Staff, Compounding Pharmacist

FIRM NAME	STREET ADDRESS
Oakdell Pharmacy, LLC	7220 Louis Pasteur Drive, Suite 176
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78229-4535	Producer of Sterile and 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION #1

Disinfecting agents and wipes used in the ISO 5 aseptic processing area are not sterile.

Specifically,

A) Your firm utilizes non-sterile disinfectants in the ISO 5 laminar flow hood (i.e. (b) (4)).

B) Your firm uses non-sterile wipes to apply disinfectants in the ISO 5 laminar flow hood.

OBSERVATION #2

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 procedure entitled, "Validation of Personnel - Sterile Compounding" (undated) documents, in part, that a total of (b) (4) vials ((b) (4)) will

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	Stephen D. Brown, Investigator	Stephen D. xBrown -S	03/29/2017

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be used to conduct media fills. Review of media fills conducted between 4/13/16 and 1/4/17 revealed that the media fills were not representative of actual production processes in that your firm failed to simulate actual production processes.

For example, your firm routinely produces sterile, injectable drug product, Papaverine HCl 15mg/ml, Phentolamine Mesylate 0.25mg/ml, Prostaglandin E1 0.006/ml, with a batch size of approximately (b) (4) vials.

In addition, your media fill dated 12/13/16 failed sterility testing. A subsequent re-test on 1/14/17 passed sterility testing. There was no investigation into the initial sterility failure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Stephen D. Brown, Investigator	Stephen D. X Brown -S	DATE ISSUED 03/29/2017