DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	02/25/2013 - 03/01/2013* FEI NUMBER 3004497213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John R. Carson, President-CEO

FIRM NAME	STREET ADDRESS
Oakdell Pharmacy, Inc	7220 Louis Pasteur Dr Ste 176
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78229-4535	Producer of Sterile Drug Products

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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written and followed.

Specifically, your firm does not have written procedures describing how aseptic operations are performed in ISO 5 and ISO 7 classified areas.

- On 2/26/2013, a pharmacist from your facility preparing an order for Vancomycin Ophthalmic drops 25mg/mL (10mL) did not sanitize gloves with (b) (4) each time he was observed carrying components from the ISO 8 classified area through the ISO 7 classified area into the ISO 5 classified laminar air-flow hood.
- On 2/26/2013, a pharmacist from your facility wearing a non-sterile lint-free labcoat rested his elbows on the benchtop of the ISO 5 laminar air-flow hood while performing aseptic manipulations of the same Vancomycin Ophthalmic drops 25mg/mL (10mL).
- On 2/26/2013, a pharmacist from your facility shook a vial of in-process drug component, (b) (4) (b) (4) expiration Jan.1, 2015), for the purpose of homogenizing the vial contents inside the working space of the ISO 5 laminar air-flow hood.

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your firm's gowning requirements described for operators working in ISO 8, ISO 7, and ISO 5 classified areas include a single pair of sterile gloves, a single pair of non-sterile shoe covers, a single non-sterile lint-free lab coats, a single hair net, and a single ear-loop face mask.

- Your firm does not have a written procedure describing the gowning requirements for aseptic operations performed in classified areas of your facility.
- On 2/26/2013, a pharmacist from your firm was performing sterile drug processing of Vancomycin Ophthamlmic drops 25mg/mL (10mL)inside the ISO 5 laminar air-flow hood wearing the garments described above.
- Exposed skin was observed around the eyes, forehead, and neck for operators processing a sterile drug.

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OBSERVATION 3

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, your firm has not evaluated the composition of equipment contact surfaces or the facility layout in order to prevent the contamination of ISO 5, ISO 7, and ISO 8 classified areas used in the production of sterile drug products.

- Your ISO 5 laminar air-flow hood workbench is constructed from particle board with a laminated surface on which sterile drug products are aseptically filled. This was confirmed by your firm's Chief of Staff on 2/26/2013.
- Your facility has a sink used for hand washing located in the ISO 8 classified area adjacent from the ISO 7 classified area inside which the ISO 5 laminar air-flow hood is used for aseptic operations of sterile drug products. The ISO 7 and ISO 8 areas are separated by a non-locking, swinging door with a visible gap.
- The smoke study performed by a contracted testing laboratory in September, 2012 for the ISO-5 laminar air-flow hood was not performed under dynamic conditions.
- The pressure differential limits tested by a contracted testing laboratory in September, 2012 for the ISO 5 laminar air-flow hood, the ISO 7 area, and the ISO 8 ANTE room were only observed during at rest conditions of operation. These pressure limits between classified rooms are not actively monitored by your firm during normal operating conditions according to your firm's Chief of Staff.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, your firm does not have a written procedure describing the rotation of cleaning agents and sporacides used to disinfect the ISO 5 laminar air-flow hood, the ISO 7 classified area, or the ISO 8 ANTE room.

- Your firm did not document an evaluation of the effectiveness of (b) (4) (b) (4) used in rotation as the exclusive cleaning agents on the equipment contact surface of the ISO 5 laminar air-flow hood workbench. These products were observed in use on 2/26/2013, and they were observed in storage in the ISO 8 classified ANTE room.
- Your firm did not document an evaluation of the effectiveness of a (b) (4) (b) (4) used in rotation as cleaning agents on the walls and floors of the ISO 7 classified areas and the ISO 8 classified areas. These products were observed in storage in the ISO 8 classified ANTE room.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm does not have a written procedure regarding the performance of environmental monitoring of ISO 5 classified areas during sterile drug processing.

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- A contract testing laboratory performs viable and non-viable monitoring of the ISO 5 laminar air-flow hood during recertification every (b) (4) only under at rest conditions. The firm has not performed a study in dynamic conditions.
- Your firm does not perform environmental monitoring of ISO 5 classified areas outside of the certification every (b) (4)
- Your firm does not perform any personnel monitoring of those operators working in ISO 5 classified areas during the production of sterile drug products.. The most recent documented performance of "fingertip" test was performed on 8/15/2012 during media fill qualifications.

OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, although your firm's management stated on 2/26/2013 that approximately 80% of compounded products are given extended beyond use dates, your firm has no written procedure to define how extending the beyond use date is validated and what specifications must be met in a stability protocol.

- On 2/27/2012 firm management stated that beyond use dates are typically assigned by your firm based on USP recommendations for low risk, medium risk, and high risk compounded products; however, if extended beyond use dates are requested by customers your firm sends drug product samples to a contract testing laboratory for stability indicating testing. No written procedure exists to define sample size or what tests are to be performed to assess the stability of these drug products.
- Your firm's pharmacist stated that anti-microbial effectiveness testing is not performed as part of your firm's stability tests on sterile drug products containing preservatives to support your labeled Beyond Use Dates.

OBSERVATION 7

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, your firm's media fill validations conducted for each pharmacist performing aseptic operations do not include all sources of potential contamination typical of normal operating conditions.

- Your firm's policy titled, "Employee Qualifications for Sterile Compounding," (undated) states that (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) Your media fill policy does not address the use of syringes as the finished drug product container, and it does not include all typical manipulations that occur under normal operating conditions--for example the opening and closing of doors between ISO 7 and ISO 8 classified areas during aseptic operations.
- Media fill validations performed in August, 2012 were performed according to the, "Employee Qualification for Sterile Compounding," policy. The same policy states that each employee shall be evaluated on his or her designated aseptic process (b) (4) Your firm does not have complete records of all employee media fill validations dating before or after August, 2012.

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02/25/2013(Mon), 02/26/2013(Tue), 02/27/2013(Wed), 03/01/2013(Fri)

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