DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/16/2016-3/11/2016*
	FEI NUMBER 2074359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Blair W. Galbreath , Director Pharmaceutical Services

FIRM NAME	STREET ADDRESS
Dignity Health - Northridge Hospital Medical Center	18300 Roscoe Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Northridge, CA 91325-4105	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

Your environmental monitoring program of the aseptic processing is inadequate in that:

A. The active viable air environmental monitoring is not conducted during daily operations. The active viable air monitoring is conducted every (b) (4)

B. The passive viable air environmental monitoring is not conducted during daily operations. The passive viable air monitoring is conducted (b) (4)

C. The non-viable air particulate environmental monitoring is not conducted during daily operations. The nonviable air monitoring is conducted every (b) (4)

D. Personnel are not monitored after each operational shift. Your firm conducts fingertips monitoring (b) (4)

OBSERVATION 2

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Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A. Your firm does not have a designated anteroom for personnel to gown before entering into the ISO 7 for processing of sterile drug product within ISO 5 laminar flow hoods. Your personnel are gowning in the (b) (4) .

B. Your firm has not qualified the "IV Room" classified ISO 7 since (b) (4) . This room contains (b) (4) ISO 5 laminar flow hoods which are used for processing of sterile drug products.

C. Your ISO 7 classified room does not have doors for the two entrances. The room has plastic strip curtains separating the ISO 7 room from the unclassified area.

D. A sink was observed inside an ISO 7 classified room. This sink is use by pharmacists and technicians to wash hands upon entering the ISO 7 area before putting on sterile gloves.

OBSERVATION 3

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

Specifically,

A. Your firm has not conducted the process simulation for the TPN production.

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B. On 02/16/16 and 02/17/16, technicians were observed moving materials and components from ISO 7 to ISO 5 without first (b) (4) .

C. On 02/16/16 and 02/17/16, technicians were observed stepping away from the ISO 5 area and returning to the ISO 5 area without gloves being sanitized.

OBSERVATION 4

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

A. No static and dynamic smoke studies conducted for the aseptic processing ISO 5 area and supporting ISO 7 room.

B. There are no pressure different gauge for pressure differential monitoring between the ISO 7 area to the unclassified area.

C. Your firm has not establish minimal airflow velocity from the ISO 7 room to the adjacent unclassified area.

OBSERVATION 5

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

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On February 16 and 17, 2016, the trolleys that hold the biohazard waste container were observed to have unknown dirt and debris on the surfaces of the trolley. These trolleys with waste containers are placed inside the ISO 7 room next to the ISO 5 laminar flow hood.

OBSERVATION 6

Clothing of personnel engaged in the manufacturing , processing , packing and holding of drug products is not appropriate for the duties they perform.

Specifically,

A. Your firm does not use sterile gowning components for pharmacists and technicians involved with the manufacturing operations within the ISO 7 and ISO 5 areas.

B. On 02/16/2016, a pharmacist was observed entering the ISO 7 room with work clothes without a gown, hairnet, and shoe covers as required by Policy #83900.816, "Compounded Sterile Pharmaceutical Preparation"

C. Disposable gowns (b) (4)
On 02/17/2016, a disposable gown was observed hanging within the ISO 7 area and (b) (4) by a technician before operating within the ISO 5 area.

D. On 2/17/2016, a technician was observed not fully gown while operating inside the ISO 7 room. Technician's street clothes were exposed.

E. On 2/17/2016, a pharmacist was observed entering the ISO 7 room with work clothes without a gown and shoe covers. The hairnet worn was observed not fully covering the hairs.

F. On 2/16/2016 and 02/17/2016, technicians were observed to have exposed skin around the eye,

head, and neck areas while they are operating within the ISO 5 area.

OBSERVATION 7

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

Specifically,

A. The ceiling within the ISO 7 room has (b) (4) fire sprinkler heads and an unsealed ceiling access door.

B. Gaps were observed between ceiling and supply air duct within the ISO 7 room.

OBSERVATION 8

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

Specifically,

Your firm does not have a stability study to support the Labetalol HCl 5 mg/ml injection beyond use date of 28 days.

OBSERVATION 9

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

Specifically,

A. Your firm does not document the use of sporicidal agent for disinfecting of the ISO 5 laminar flow hoods which are used for aseptic processing of sterile drug products. The sporicidal agent was reported to be used (b) (4)

B. The sanitizer and disinfectant effectiveness studies have not been conducted to determine whether the solution use is effective for the intended use. The contact times have not been determine for the sterile (b) (4) and sporicidal agent use within the ISO 5 laminar flow hoods.

C. Sterile wipes are not used within the ISO 5 area.

OBSERVATION 10

There is a failure to thoroughly review whether or not the batch has been already distributed.

Specifically,

A. Your firm does not investigate the positive results from personnel fingertip monitoring. Any personnel with positive results are retested.

B. No investigation was conducted after the results of the (b) (4) sampling conducted March 9, 2015 found spores within the (b) (4) from Basidiospores and Penicillium/Aspergillus types. The corrective action was to (b) (4) .

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*DATES OF INSPECTION

2/16/2016(Tue),2/17/2016(Wed),2/22/2016(Mon),2/23/2016(Tue),2/26/2016(Fri),3/11/2016(Fri)

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