DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	02/19/2013 - 02/22/2013
	FEI NUMBER 1000305893

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edgar L. Mendaros, Director of Quality Assurance

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services Inc.	821 N Lessing St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chicago, IL 60622-5424	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

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

The firm does not always recognize and investigate trends in quality deficiencies in a timely manner.

a. Since February 2010 the firm has been aware of recurring leaks in sterile injectable Total Parenteral Nutrition (TPN) bags at all of its facilities, yet the firm did not open an investigation into the trend until August 2012. For example, at this facility there were 22 complaints for leaking TPN bags from 2/1/2012 to 2/19/2013. Furthermore, the firm has not fully evaluated potential corrective and preventive actions to deal with these leaks. For example, it has mainly tried to persuade the manufacturer of the sterile bags it uses to investigate potential causes and pursue corrections, yet it has not evaluated its own process of checking TPN bags for leaks before releasing them.

b. Since February 2012 the firm has rejected three out of the (b) batches of Sodium Citrate 40% Solution it has produced for testing below the potency specification, yet it has not opened an investigation into this trend.

OBSERVATION 2

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

Specifically,

For sterile drug processing in the ISO-5 zones (in accordance with SOP-CAPS-4000172, "Environmental Monitoring," ver. 9.0, sections # 4.8.2 and 4.9.1 and 4.11.3.A and 4.7.1.E): air bioburden sampling (b) (4) and surface bioburden sampling and glove fingertip bioburden sampling and air particulate matter sampling are performed on a (b) (4) basis, instead of daily.

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	Russell K. Riley, Investigator Bruce H. Mccullough, Investigator	02/22/2013

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OBSERVATION 3

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

Specifically,

In accordance with SOP-CAPS-4000171, "Gowning Requirements," ver. 5.0, the apparel worn by personnel working in the ISO-7 cleanrooms still leaves exposed skin areas on the forehead, around the eyes, and on the necks of the workers. Hoods and goggles are not used. The hairnets, beard covers, and face masks worn in the ISO-7 cleanrooms are non-sterile apparel.

OBSERVATION 4

There was a failure to handle and store components at all times in a manner to prevent contamination.

Specifically,

On 2/19/2013 I (RKR) observed a bag of Citric Acid lot (b) (4) [redacted] stored in the warehouse with a hole in the bag which exposed the citric acid inside to the unclassified air. The warehouse also has a dock door where materials are picked up and delivered by truck. Citric Acid is a component in the production of Sodium Citrate 40% Solution, a sterile drug which is used in the production of sterile injectable drugs.

OBSERVATION 5

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

Specifically,

The firm does not continuously monitor air pressure differentials during production of sterile injectable drug products.

OBSERVATION 6

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

Specifically,

The firm has not challenged with product-specific bacterial retention studies the filters used to sterilize sterile injectable drug

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products made from non-sterile components.

OBSERVATION 7

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically,

The firm does not have recent stability data supporting the Beyond Use Dates (BUD) of some of its sterile injectable drug products.

a. The most recent stability data for Tromethamine 0.6M Solution is from 2000. The BUD for this product is 91 days at 2-8 C.

b. The most recent sterility, endotoxin, and particulate matter stability data for Cardioplegia solutions is from 2002. The BUD for these products varies between 14 and 30 days (depending on the formula) at 2-8 C.

HCR 2/22/2013

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