DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	02/01/2016 - 02/05/2016
	FEI NUMBER 3006616657

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Michael A. Koch, Vice President Marketing and Professional Services

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	16800 Aston Street, Suite 150
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Irvine, CA 92606	Corporate Headquarters

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

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,
During an interview with the Director of Quality Assurance, he stated that he has ultimate authority regarding quality issues at all 24 CAPS sites. The CAPS Operating Procedure, COP-CAPS-4000004, dated 06-03-2014 and entitled: Quality - Upper Management Notification, describes the types of deviations that must be reported to upper management including the Director of Quality Assurance. However, this procedure is insufficient in that it does not fully describe all of the roles and responsibilities of the Quality Control Unit at corporate headquarters over all of the 24 CAPS sites.

OBSERVATION 2

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product.

Specifically,
In Complaint Investigation 37-150123-015, notification was provided that indicated a cardioplegia drug was not working (did not stop the heart when administered during surgery). The firm's investigation revealed that IV Technician (b) (4), (b) (6) was involved in producing the drugs in all lots in the complaint supplied by the hospital. The Cardioplegia Induction(b) (4) was from lots #37-80463-0-5, #37-80463-0-6, and #37-79031-0-20 made on 1/13/15, 1/13/15, and 1/8/15 respectively. The conclusion was classified as "investigation no issue". Yet, the investigation did not extend into any other batches that may have been produced by the same person or evaluate the quality of the components used. None of the remaining bags from the lot were returned, therefore, further testing could not be completed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stacie A. Woods, Investigator Djamila Harouaka, Investigator Lance A. Finnical, Investigator	02/05/2016

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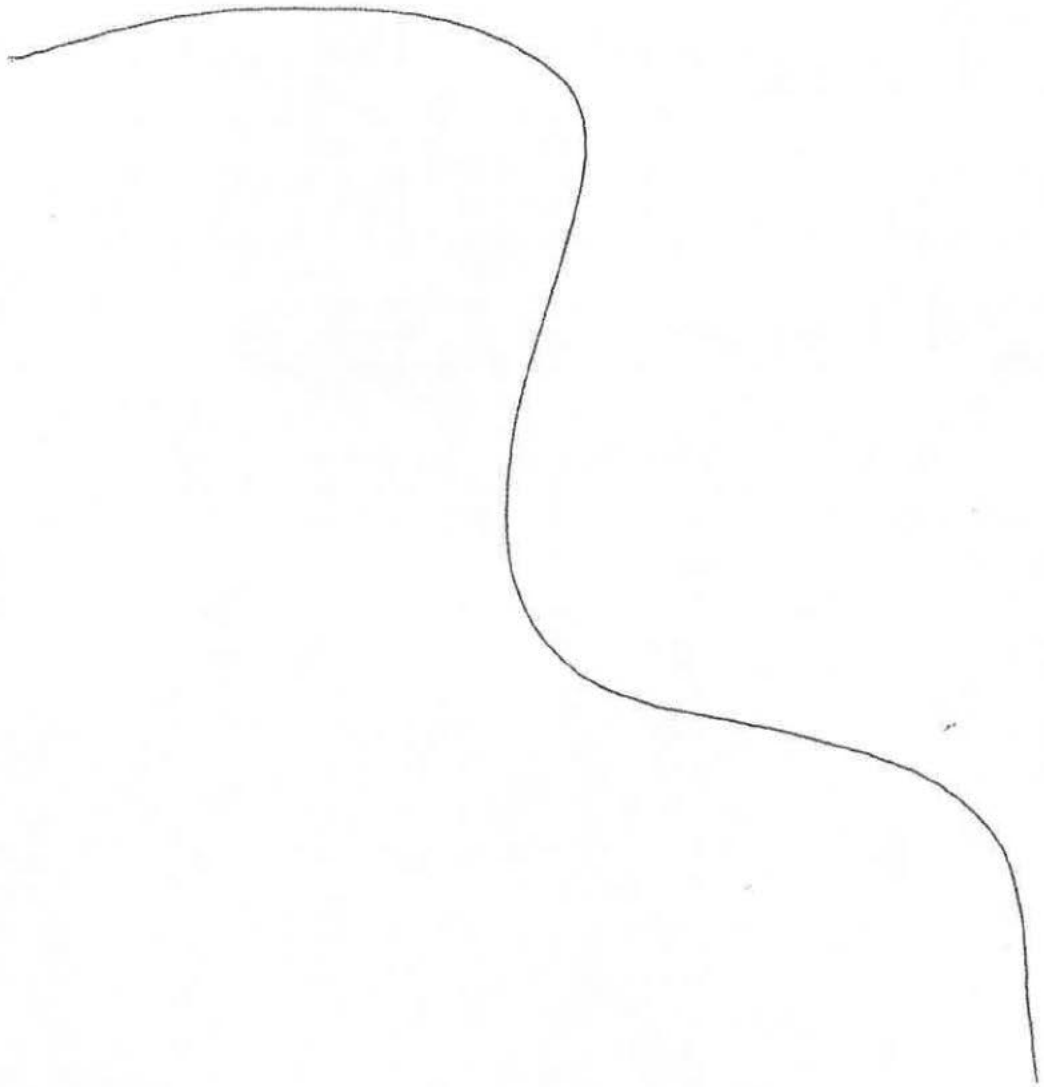

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