DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 Phone #615/366-7801	01/09/07 - 01/19/07
	FEI NUMBER 1000221951

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Leslie E. Vanderver, R.Ph. / Director of Pharmacy

FIRM NAME	STREET ADDRESS
Central Admixture Pharmacy Services, Inc.	211 Summit Parkway, Suite 122
CITY, STATE AND ZIP CODE Homewood, AL 35209	TYPE OF ESTABLISHMENT INSPECTED Compounding Pharmacy / Drug Manufacturer

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) (WE) OBSERVED:

Item #1

The designated quality control unit does not have the authority or responsibility to approve/reject raw materials, labeling, finished product release, and batch records. Per SOP #A0201 section 2.4 entitled "Organization and Responsibilities" these tasks are assigned to and are in fact carried out by (b) (4) and not to the designated quality control unit. For example, per Complaint #2006090 dated 05/18/06, the firm processed/released (b) (4) bags of Oxytocin in 500ml Dextrose 5% Lactated Ringers labeled as Oxytocin in 1000ml Lactated Ringers. This product was released after review by (b) (4) No further review was conducted by the QC unit prior to the product being distributed.

Item #2

A review of the firm's product complaint files noted that the firm is not following SOP #F0400 section 4.3 entitled "Prescription Entry/Checking/ Labeling regarding the issuance and verification of finished drug product labeling. Three of eleven product complaints reviewed since the previous inspection dated 09/30/05 indicated a failure of the pharmacist's QC review to detect labeling discrepancies which allowed the release of three lots of mislabeled product.

Item #3

Firm did not follow SOP #E0200 entitled "Material Receiving, Handling & Storage" dated 03/08/05 section 4.3. The firm failed to identify raw material received in regards to a case of 5% dextrose solution received on 10/11/06. This resulted in this case of 5% dextrose solution being accepted as a case of citrate phosphate dextrose solution. It was ultimately utilized in various Cardioplegia formulations as citrate phosphate dextrose resulting in the omission of citrate phosphate dextrose from some formulations. This SOP was revised on 11/11/06, however section 4.3 remains unchanged.

Item #4

Batch production records do not include all lot numbers of raw ingredients that are used in each finished drug product. The only lot numbers recorded are those for MSA/MSG and Tromethamine if used.

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Item #5

The firm does not perform sterility testing on each marketed finished product batch of injectable drug product produced. Sterility testing is only performed on a (b) (4) basis.

Item #6

The firm does not have a standard operating procedure that addresses corrective actions/investigations for active ingredients found to be out of specification in finished drug products.

Item #7

According to manufacture's recommended temperature storage specification, Mannitol should be stored at 15-30 degrees C. The firm's own specifications for the Mannitol (b) (4) are from (b) (4) degrees C. The firm has not validated this specification. The firm did not take corrective action when temperature deviations from their own specifications occurred in the (b) (4) used to store the raw ingredient Mannitol. For the period of 01/2006 to 12/2006 a review of (b) (4) Temperature Monitoring logs for Mannitol (b) (4) noted at least 135 instances where the temperature was out of specification ((b) (4) degrees C). Mannitol is routinely used in the production of finished drug products.

In addition for the period from 01/2006 to 12/2006 a review of (b) (4) Temperature Monitoring logs for (b) (4) #1 used for environmental monitoring noted at least 44 instances where the temperature was out of specification ((b) (4) degrees C). The firm's own specifications for this (b) (4) are from (b) (4) degrees C.

Item #8

Environmental monitoring testing does not include positive controls for media.

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Item #9

The firm utilizes water labeled as "(b) (4) " in lieu of "Sterile Water for Injection" to compound sterile drug products.

Item #10

Weights used by the firm to perform (b) (4) calibration checks on scales, used during filling of finished drug product bags, are not calibrated.

Item #11

Proper aseptic techniques are not always followed in the processing of sterile drug products. For example:

a) On 01/10/07, an employee in the Cardioplegia compounding room was noted to discard some plastic tubing and to miss the trash can. This employee was then noted to pick up this tubing from the floor. This employee was immediately instructed by a member of management who was accompanying us to re-glove.

b) On 01/10/07, an employee in the Cardioplegia compounding room was noted to stretch his arms above his head and rapidly lower them to and touch his waist. The member of management who was accompanying us immediately instructed him to sanitize his gloves.

Item #12

On 01/11/07, a Radio/CD player was observed in the Cardioplegia and Total Parenteral Nutrition sterile compounding rooms. Management policy as related to us was that it was okay to bring in personal items as long as these items could be sterilized. No records documenting the sterilization of this personal equipment exist.

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Item #13

The ceiling in the Class 10,000 Cardioplegia compounding room is not free from cracks and crevices. On 01/10/07 we noted several cracks between the wall and ceiling junction. Also, one of the protective lighting covers located in the ceiling was noted to be cracked on 01/10/07.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."