DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	5/20/2016-6/3/2016*
	FEI NUMBER 3012327563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Raymond P. Jajeh, Pharm.D. , Owner

FIRM NAME	STREET ADDRESS
Jajco, Inc. DBA Anchor Drugs Pharmacy	161 S Spruce Ave
CITY, STATE, ZIP CODE, COUNTRY South San Francisco, CA 94080-4517	TYPE ESTABLISHMENT INSPECTED 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

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

Specifically, your firm uses non-sterile gowning components and exposes bare hands during the aseptic operation performed in the Clean Room.

On 05/20/2016, your "Compounding Pharmacist" was observed aseptically processing your sterile drug product, Atropine 0.01% Solution, Lot #05/20/2016:1031, with exposed skin on the face and neck. Non-sterile gowning components such disposable lab coat, dust mask, street reading glasses and hair net were worn by your "Compounding Pharmacist" during the sterile operation. After the pre-production cleaning of the ISO 5 Laminar Flow Hood, we observed your "Compounding Pharmacist" exposing (b) (5), (b) (7) (C) bare hands directly inside the ISO 5 Laminar Flow Hood after taking off (b) (5), (b) (7) (C) used sterile gloves.

OBSERVATION 2

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

Specifically, your environmental and personnel monitoring program is deficient, in that there is no assurance that the production areas are adequately controlled. Examples include, but are not limited to the following:

A.) On 5/20/2016, your "Compounding Pharmacist" stated that environmental and personnel monitoring is performed (b) (4) for the (b) (4)

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(b) (4). This monitoring frequency is also stated in written procedure titled, *SOP (Standard Operating Procedure) 3.030, Environmental Monitoring of the Clean Room Facility, Version 2.0, Date Effective 10/19/2015* under Section 6.2: "(b) (4)" Additionally, this practice is confirmed on the Environmental Monitoring records dated from January 2015 to the present.

B.) On 5/25/2016, your "Compounding Pharmacist" and Technician stated that positive controls on the (b) (4) plates used for Environmental Monitoring are performed (b) (4). Your firm failed to specify the use of positive controls to ensure that incubation conditions are fit for use.

C.) On 5/25/2016, your "Compounding Pharmacist" stated that your Environmental Monitoring program (b) (4). No mold or yeast testing is performed for Environmental Monitoring. This is also evident in the incubation period (b) (4) which are shown by your Environmental Monitoring records dated from January 2015 to the present.

OBSERVATION 3

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

Specifically, your firm has not established written procedures for your sterile operation which include but are not limited to the following:

A.) Smoke studies have never been performed on the ISO 5 Laminar Flow Hood.

B.) Validation studies of the (b) (4), have not been performed for your sterile products, Phenol 5% in Cottonseed Oil and Glycerin 100% Ophthalmic Solution to assure that the (b) (4) will consistently produce a product meeting its pre-determined specifications and quality attributes. Your procedures required these products to be (b) (4)

C.) There is no assurance that the environmental and personnel monitoring (b) (4) plates are producing reliable results. (b) (4) lot (b) (4) was documented to be incubated at (b) (4) in the same incubator where the environmental (b) (4) plates sampled from (b) (4), and personnel monitoring were incubated on (b) (4) (b) (4). During the inspection, your "Compounding Pharmacist" confirmed and stated that when (b) (4) the firm also incubates the environmental and personnel monitoring (b) (4)

D.) Media fill records dated from January 2013 to the present were reviewed and revealed that Media fills did not simulate the actual processing for your sterile products. For example, media fills consist of (b) (4) when an actual compounding drug lot size can consist (b) (4)

E.) Media fills were not conducted in accordance to written procedure titled, *SOP 2.030 Sterile Compounding Personnel Qualification, Version Number 2.0, Date Effective 10/19/2015* under Section 9.4.2: "Each employee shall be evaluated on his or her designated aseptic technique (b) (4) . For example, media fills were not performed in November 2015, (b) (4)

F.) The contact times of sporicidal and disinfectant agents that are used during the cleaning procedures of the ISO 5 Laminar Flow Hood are not specified in any written procedures. On 05/20/2016, we observed the "Compounding Pharmacist" (b) (4)

OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy and 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.

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Specifically, your firm failed to perform and document investigations of a recalled sterile drug product and of out-of-specification viable air monitoring readings. Examples include, but are not limited to:

A.) The drug product, Cyclopentolate/Phenylephrine/Tropicamide/Propatacaine ½.5/1/0.5% ophthalmic drops, Lot# 11/18/2014:1902, was compounded at your firm on 11/18/2014 and recalled by your firm on 11/25/2014 after a "positive(b) (4) [result/sterility failure] at 4 days". There is no available documentation to show:

- Root cause of this sterility test failure;
- Investigation of additional lots of Cyclopentolate/Phenylephrine/Tropicamide/Propatacaine ½.5/1/0.5% ophthalmic drops to determine product risk;
- Investigation of components, containers/closures, facilities, personnel, and/or other elements that could contribute to the risk to any sterile drug products at your firm.

B.) The review of clean-room certification records performed by service provider, (b) (4) revealed that (b) (4) failed viable air monitoring certifications on (b) (4), where 9 bacterial colonies were recovered and identified. This specification was (b) (4) without a record of an investigation. Your firm continued to perform sterile operations during this timeframe.

C.) The review of clean-room certification records performed by (b) (4) revealed that the (b) (4) failed viable air monitoring certifications on (b) (4) These specifications were (b) (4), (b) (4) without a record of an investigation. Your firm continued to perform sterile operations during this time frame.

D.) Your firm failed to investigate the following drug products that did not meet specifications:

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- Lido/Epi, Lot (b) (4) had potency test results for epinephrine and lidocaine of 79.56% and 90.38%, respectively. Your established specifications for epinephrine and lidocaine are (b) (4) respectively. According to your "Compounding Pharmacist", this product lot was distributed to patient(s) without conducting a product investigation.

- Methimazole, Lot #12/24/2015:1004, had a potency test result of 88.7%, while your firm's established specifications are (b) (4) . Your "Compounding Pharmacist" stated that this product lot had already been distributed to patient(s) before the test result was obtained. No product impact evaluation was performed.

OBSERVATION 5

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

Specifically, your firm lacks a system of monitoring pressure differential limits in the Clean Room to detect atypical changes in air pressure that can compromise the Clean Room environment when not in use and during production. Examples include, but are not limited to the following:

A.) The pressure differential limits for the Clean Room and the Ante Room are checked and recorded (b) (4) . Your firm does not monitor pressure differential limits during your sterile drug compounding operations.

B.) The written procedure titled, *SOP 3.020, Cleaning and Maintenance of the Clean Room Facility, Version 3.0, Date Effective 02/01/2015* specifies under Section 9.8.1.4 that "the pressure [the pressure differential (b) (4) However, *SOP 3.020* does not address what the procedure is to handle limits that are out of specification.

C.) In the (b) (4) *Monitoring of the Non-sterile Compounding Area* (b) (4) and *Monitoring of the Non-sterile Compounding Area* (b) (4) logbooks, there were 6 data points in which the Clean Room pressure did not meet the specification set in *SOP 3.020*, (b) (4) The pressure

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differential in the Clean Room ((b) (4) , indicated in the table below) appeared to be negative (less than the value of the pressure of (b) (4) , indicated in the table below). Examples include, but are not limited to:

Date	(b) (4)	
(b) (4)	0.03 "WC	0.01 "WC
	0.02 "WC	0.015 "WC
	0.035 "WC	0.015 "WC
	0.015 "WC	0.01 "WC
	0.01 "WC	0.01 "WC
	0.03 "WC	0.015 "WC

No excursion report was generated to capture this incident.

D.) The placement of air return vents in relation to HEPA filters do not ensure proper clean air flow. Specifically:

- In the ISO 7 Clean Room (b) (4) HEPA filters are located on the ceiling and the air return vent is located on the high wall exiting to the ISO 8 Ante Room.
- In the ISO 8 Ante Room, the (b) (4) HEPA filters on the ceiling are located approximately (b) (4) away from the (b) (4) air return vents.

OBSERVATION 6

Routine calibration, inspection and checking of equipment is not performed according to a written program designed to assure proper performance.

Specifically, your firm failed to ensure that all equipment used in the sterile operation can perform for its intended use.

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A.) Equipment qualification has not been executed for the (b) (4) and the (b) (4) Incubator to ensure that the equipment can achieve and maintain appropriate (b) (4) set forth in your established (b) (4) According to your "Compounding Pharmacist", the (b) (4) have not been calibrated and/or maintained. During the inspection on 05/20/2016, we observed the (b) (4) (b) (4) The (b) (4) Thermometer has not been verified against the traceable standard.

B.) Written procedures have not been established for the calibration and maintenance of your (b) (4) The Formula Worksheets for Trimix 10mcg/30mcg/1mg/ml Solution and Bimix 30mg/1mg/ml Solution indicate that the compounded product is (b) (4) into sterile vials or sterile syringes. Your firm has never performed calibration of the (b) (4) . Additionally, written procedures for (b) (4) have not been established.

OBSERVATION 7

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

Specifically, your firm has no scientific data to justify the assigned Beyond Use Date (BUD) for your sterile products which include but are not limited to:

A.) Lidocaine Hydrochloride with Epinephrine 1% with 8.4% sodium bicarbonate was assigned a BUD of 10 days at refrigerated temperature of 2°C-8°C. The literature article source for the BUD provided during the inspection concluded that (b) (4) . No potency testing has been performed to ensure that Lidocaine Hydrochloride with Epinephrine 1% does not degrade over the extended BUD for 10 days.

B.) Trimix products, in various strengths, were assigned a BUD of 30 days at refrigerated temperature of 2°C-8°C and 180 days at freezer temperature of -23°C. Your firm obtained the BUD for Trimix from

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your vendor; however, the formulation identified in the BUD Study from your vendor is not equivalent to the formulation for your Trimix. Your formulation indicated that (b) (4) is (b) (4) (b) (4). Meanwhile, the formulation identified in the BUD Study (b) (4) does not include (b) (4) (b) (4) Your firm has not performed potency testing and/or anti-microbial effectiveness testing to ensure that Trimix does not degrade over the extended BUD and to evaluate whether the preservative system can retain throughout the product shelf life.

C.) Your firm has no scientific data to justify the assigned BUD of 30 days at refrigerated temperature of 2°C-8°C and 180 days at freezer temperature of -23°C for your sterile products, Bimix, in various strengths. Additionally, no potency testing and/or anti-microbial effectiveness testing have been performed over the extended BUD of 30 days at refrigerated temperature of 2°C-8°C and 180 days at freezer temperature of -23°C.

***DATES OF INSPECTION**
5/20/2016(Fri),5/23/2016(Mon),5/24/2016(Tue),5/25/2016(Wed),5/26/2016(Thu),6/03/2016(Fri)

X Anh Lac 6/3/2016
Anh Lac
Investigator
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Henry K Lau
Microbiologist (CTNH)
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