DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	06/03/2013 - 06/19/2013* FEI NUMBER 3010223213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Alfred Corrado, Pharmacist/Co-Owner

FIRM NAME	STREET ADDRESS
Americare Compounding, LLC.	319 Nassau Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Garden City South, NY 11530	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

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has distributed (b) medication orders, from lots processed in the past year. For the sterile drug products, the following testing was not performed:

a. Assay or product identification testing for any sterile injectable or sterile ophthalmic drug product produced.

b. Sterility testing for all drug products produced is not performed. Only one drug product, Avastin injectable syringe, is tested for sterility.

c. Endotoxin testing data is not available for any lot of sterile drug products produced.

OBSERVATION 2

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically, you produce injectable drug products, sterile ophthalmic solutions and other drug products. The beyond use dates assigned to the drug products are not supported by stability studies conducted by your firm. There is no assurance, with the lack of appropriate scientific data, that your sterile drug products will remain sterile or maintain potency throughout the expiry period. You solely rely on scientific literature or vendor supplied information to establish beyond use dates up to 30 days for sterile drug products.

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	James A. Liubicich, Investigator James A. Liubicich	06/19/2013

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OBSERVATION 3

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

Specifically, for the processing of sterile drug products whether aseptically and/or terminally sterilized, these sterilization methods have not been validated. No media fills/process simulations have been performed.

OBSERVATION 4

The operations relating to the processing and packing of penicillin are not performed in facilities separate from those used for other drug products for human use.

Specifically, your firm is processing Penicillin, such as Penicillin Ophthalmic solution, in the same cleanroom with your non-penicillin products. The absence of a structurally isolated area creates the potential that accidental breakage of vials of penicillin powder could contaminate your other sterile drug products.

OBSERVATION 5

Air-handling systems for the processing and packing of penicillin are not completely separate from those for other drug products for human use.

Specifically, Penicillin drug products are not processed under a separate air handling system from those used for other sterile drugs.

OBSERVATION 6

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically, there are no separate facilities for processing operations to prevent contamination from beta-Lactam non-penicillin drugs. Such drugs are versions of cephalosporin injectables as Ceftazidime 2.25% syringe. These beta-Lactam powders are processed on the same work station as sterile non beta-Lactam drugs in the same clean room.

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OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically, your firm lacks adequate environmental monitoring data to support that the capabilities of its cleanroom can maintain ISO 5 (Class 100) conditions at the (b) work stations, the ISO 7 (Class 10,000) conditions in the surrounding area, and the ISO 7 (Class 10,000) conditions in the gowning room (anteroom) given the following design limitations and practices.

a. The pass through to the aseptic processing clean room serves as the entrance and exit for sterile drug products, containers and closures, etc. from an unclassified surrounding area.

b. Articles entering the pass through to the clean rooms are not disinfected before introduction.

c. There are a sink, trays, cartons, spray bottles, and a wastebasket with apparently used hair nets and other materials in the ISO 7 anteroom which is located in between adjacent ISO 7 clean rooms.

d. Smoke studies were not performed under dynamic conditions to verify that operators and processing equipment do not alter or impede the unidirectional cascade of air from the HEPA filters to the ISO 5 workstations where sterile drug products are opened and manipulated, and to the rest of the ISO 7 clean rooms.

OBSERVATION 8

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

Specifically, the gowning worn by employees entering the ISO 7 cleanroom is stored in the ISO 7 anteroom. The gown can be reused during an operational day by hanging it within the ISO 7 gowning room and is re-used during the week. The mouth and nose are covered by a mask and a hair net is used allowing exposed skin over the critical ISO 5 work stations.

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OBSERVATION 9

Equipment and utensils are not sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, the firm does not use sporicidal cleaning agents at the workstations inside the ISO 5 hoods.

OBSERVATION 10

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

Specifically, environmental monitoring is not performed on a frequent basis or during dynamic conditions.

a. Each workstation, inside the ISO 5 hood, is not tested appropriately for viable microorganisms and non-viable particulates on a frequent basis. Environmental monitoring of each workstation is performed (b) (4) by the firm and by an outside contractor every (b) (4) by swabbing the surfaces.

b. Environmental monitoring of personnel is not performed each day of production. There is no sampling of operator's gloves.

c. Environmental monitoring has not been performed for active viable monitoring of the air in the clean rooms.

OBSERVATION 11

Reserve drug product samples are not retained and stored under conditions consistent with product labeling.

Specifically, you do not collect or store retains for any of the sterile drug products that you produce, nor for non-sterile drug products. In the processing of Avastin syringes, retains can be available if the complete lot is not fully distributed.

OBSERVATION 12

Appears this way on the original.

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, the firm does not have written procedures for any of the operations conducted at the firm including sterile drug processing, testing procedures, stability program, quality assurance, etc.

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*** DATES OF INSPECTION:**
06/03/2013(Mon), 06/06/2013(Thu), 06/10/2013(Mon), 06/19/2013(Wed)

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