DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	01/30/2014 - 02/04/2014* FEI NUMBER 3010633613

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Daoud A. Zayed, Owner

FIRM NAME	STREET ADDRESS
Eastern Pharmacy, Inc.	2046 W Silver Springs Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ocala, FL 34475	Producer of sterile drugs

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

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

Specifically for the repackaging of Avastin (Bevacizumab) and Lucentis (Ranibizumab) drug products from commercial, sterile, single-use vials into approximately (b) (4) individual syringes (0.05mL) ((b) (4)-Avastin & (b) (4)-Lucentis) from June 2013 to December 2013:

A. You stated your firm has no written procedures (validation) for the aseptic process of repackaging sterile product to ensure that the repackaging operation can be performed under conditions that do not potentially contaminate the finished drug product.
B. You stated your firm has no written procedures for environmental monitoring. You have never performed environmental monitoring to provide assurance of aseptic conditions during your repackaging operations. In addition, you stated to us that while performing the repackaging of Avastin (Bevacizumab) and Lucentis (Ranibizumab) under the laminar air flow hood, that you never turned the hood on and that you only used the hood for the available working surface.
C. You stated your firm has no written procedures for gowning or how to qualify personnel for gowning. You were not able to provide any documentation that indicates you had performed a gowning qualification prior to initiating the repackaging process in June of 2013. You also stated that the gowns you used during the repackaging operations were not sterile.
D. You stated your firm has no written procedures for conducting media fills or qualifying personnel. You stated to us that you had not conducted a media fill prior to initiating the repackaging operations in June 2013 to demonstrate that you have adequate aseptic technique to prevent the possible contamination of the finished drug products.
E. You stated your firm has no written procedures for cleaning equipment used in aseptic processes. You stated to us that you purchase [redacted] (b) (4) from a local drug store as your sole cleaning agent.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael H. Tollon, Investigator Carla A. Norris, Investigator	02/04/2014

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OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically for the repackaging of Avastin (Bevacizumab) and Lucentis (Ranibizumab) drug products from commercial, sterile, single-use vials into approximately (b) (4) individual syringes (0.05mL) ((b) (4)-Avastin & (b) (4)-Lucentis) from June 2013 to December 2013:

A. Your firm's aseptic processing area is inadequate based on the following observations:
   1. The ceiling is not smooth or sealed which does not allow adequate cleaning.
   2. No door or closure is installed to separate the aseptic area from the common pharmacy area.
   3. No temperature and humidity controls are in place to ensure the environment is suitable for conducting sterile repackaging processes.
   4. No system for monitoring environmental conditions to ensure the environment is suitable for conducting sterile repackaging processes.
   5. No air supply is filtered through high-efficiency particulate air filters under positive pressure to ensure the environment is suitable for conducting sterile repackaging processes.

B. You stated your firm's laminar hood located in your aseptic processing area has not been qualified, certified, or determined to be operational for its intended use during the repackaging of sterile drug products according to yourself.

C. Your firm's cleaning procedure and cleaning agents are not adequate in that you are only using (b) (4) to clean your aseptic processing surfaces. This method for cleaning has not been assessed to ensure potential contaminants are adequately removed from surfaces in the areas where repackaging of sterile drug products is performed.

D. Your firm's gowning practices are not adequate in that you are using non-sterile gowns while repackaging sterile drug products and you did not have any gowns on site to present to us nor could provide any documentation proving you ever had gowns at your facility. Furthermore, you stated that you used sterile gloves during the repackaging of sterile drug products; however we could not verify this practice, since you did not currently have any sterile gloves, could not provide any documentation that you ever had sterile gloves at your facility and could only present non-sterile gloves to us during this inspection.

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OBSERVATION 3

Employees engaged in the processing and packing of a drug product lack the education, training, and experience required to perform their assigned functions.

Specifically, you could not provide any training or qualification of your aseptic technique or gowning practices other than your verbal declarations of [redacted] (b) (6) and that your last media fill was completed in 2002 at a previous employer.

OBSERVATION 4

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically, your firm did not conduct any finished product testing including sterility or endotoxin nor do you have finished product specifications for the release of approximately (b) (4) syringes (0.05mL) of Avastin (Bevacizumab) and (b) (4) syringes of Lucentis (Ranibizumab) sterile injectable products (SIPs) that were repacked from single-use vials of Avastin and Lucentis from June 2013 to December 2013.

OBSERVATION 5

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

Specifically, your firm does not have an adequate written testing program designed to assess the stability characteristics of drug products in order to determine appropriate storage conditions and expiration dates. In addition, your firm could not provide any stability data to support a beyond-use-date (BUD) of 30 days for the Avastin and Lucentis finished product syringes your firm repackaged and labeled.

This includes the repackaging of Avastin (Bevacizumab) and Lucentis (Ranibizumab) drug products from commercial, sterile, single-use vials into approximately (b) (4) individual syringes (0.05mL) ((b) (4)-Avastin & (b) (4)-Lucentis) from June 2013 to December 2013.

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OBSERVATION 6

Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically for the ~ (b) (4) syringes that your firm prepared from Avastin (Bevacizumab) and Lucentis (Ranibizumab) drug products from commercial, sterile, single-use vials; you failed to prepare batch production and control records with complete information relating to the production and control of each batch of drug product. For example, your firm did not document and could not provide the number of containers (i.e. syringes and vials) filled per batch.

OBSERVATION 7

Procedures describing the handling of all written and oral complaints regarding a drug product are not established, written, and followed.

In December 2013, you stated that you were informed by [redacted] (b) (4) that one or two patients had eye infections. However, as of January 30, 2014, the complaints were not logged and your firm did not have documentation for a complaint investigation.

*** DATES OF INSPECTION:**
01/30/2014(Thu), 02/04/2014(Tue)

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