DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New Orleans District Office 404 BNA Drive, Bldg. 200, Ste. 500 Nashville, TN 37217 (615) 366-7801 Industry Information: www.fda.gov/oc/industry	8/3/2015 - 8/21/2015*
	FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Haleigh J. Cawood, Quality Manager

FIRM NAME	STREET ADDRESS
Eagle Pharmacy, Inc	2200 Riverchase Center, Suite 675
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Hoover, AL 35244	Outsourcing Facility

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:

OBSERVATION 1

There is a failure to thoroughly review 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.

Specifically, two injectable drug products were released and distributed after the receipt of failing potency testing.

a) Lipo B, Lot 07072015LIPO, was compounded on 7/7/2015. Out of the (b) (4) - 10 mL vials produced, (b) (4) were sent for testing. Potency results were reported on 7/23/2015 and documented one of the active ingredients, methylcobalamin, was not detected in the product. An undated investigation determined the methylcobalamin degraded. The product insert was changed to remove methylcobalamin from the active ingredients with a note stating the product contains traces of methylcobalamin. This product was released on 7/23/2015 and first distributed on 7/27/2015. As of 8/14/2015, (b) (4) vials have been distributed.

b) Vitachrom, Lot 07012015VC, was compounded on 7/1/2015. Out of the (b) (4) 10 mL vials produced, (b) (4) were sent for testing. Potency results were reported on 7/28/2015 and documented one of the active ingredients, Riboflavin - 5 - Phosphate Sodium, USP, was found to be at approximately 80% of the expected potency. An undated investigation determined a process error should be added to the amount of Riboflavin in the formulation of Vitachrom. The product insert was changed to adjust the amount of Riboflavin present in the product based on the test result. This product was released on 7/28/2015 and first distributed on 7/23/2015. As of 8/14/2015, (b) (4) vials have been distributed.

OBSERVATION 2

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

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	Samantha J. Bradley	Samantha J. Bradley, Investigator	08/21/2015

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Specifically,

a) Injectable drug suspensions are sterilized in a (b) (4), (b) (4), in the ISO 7 Lab prior to being aseptically filled into vials in the ISO 5 compounding room. The validation for this process, approved 6/2/2015, supports (b) (4). On 7/15/15, the (b) (4) was (b) (4) of methylprednisolone (b) (4). The validation data does not support the process for this (b) (4).

b) On 8/4/2015, bulk Ketorolac Tromethamine, Lot 08042015KT, was left in an uncovered 5 L beaker during (b) (4) the ISO 5 compounding room, transfer onto the ISO 5 work surface, and during (b) (4) into a sterile IV bag.

c) On 8/4/2015, during observation of compounding for Ketorolac Tromethamine, Lot 08042015KT:
- The operator was observed to fill (b) (4) product into vials while (b) (6) arm was moving over empty, sterile, depyrogenated vials.
- The operator was observed to drop (b) (6) hands below the table (air flow), rest (b) (6) hands on the critical work surface, and handle objects outside of the immediate work area without re-sanitizing (b) (6) hands prior to entry back into the critical ISO 5 work area.
- Materials were transferred onto the critical work surface from the storage shelf without being sanitized.

d) Smoke studies are not performed under dynamic conditions.

e) The (b) (4) used for (b) (4) has no documentation of calibration.

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, airflow over the ISO 5 work surface is not laminar. The (b) (4) ISO 5 "hood" is composed of (b)

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HEPA (b) (4) and (b) stainless steel tables acting as the work surface. The tables do not fit the length of the wall exactly and leave a gap of approximately 8 inches at one end. During review of the smoke study performed on 5/8/2015, I observed smoke moving back towards the HEPA filters along the adjoining line between tables. Smoke was also observed to accumulate and sit in the gap between the table and wall.

OBSERVATION 4

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, compounding for Ketorolac Tromethamine, Lot 08042015KT, was observed on 8/4/2015 and the following conditions were noted:

a) An operator was observed to wear the same sterile mask between the ISO 7 Lab and ISO 5 Compounding room. The operator moved between rooms with the same mask as follows: ISO 8 (Ante Room), to ISO 7 (Lab), to ISO 8 (Ante Room), to ISO 7 (Vestibule Room), to ISO 5 (Compounding Room). Procedure states a new sterile mask be donned (b) (4)

b) Personnel enter the ISO 5 compounding room from the ISO 7 vestibule room without wearing gloves. Sterile gloves are donned after entry in the ISO 5 room.

c) Operators cheeks and necks were observed to be exposed during operations in the ISO 5 compounding room.

d) Gowning for aseptic operations does not include the use of sterilized goggles.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

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a) Non-sterile, non-shedding wipes are used in the ISO 5 clean room.

b) On 8/4/2015, I noted approximately 8 inches of the edge of each stainless steel table was not cleaned and sanitized during room set-up. These tables comprise the ISO 5 work surface.

OBSERVATION 6

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

Specifically, (b) (4) plates, used for personnel and environmental monitoring, do not contain disinfectant neutralizers, resulting in potentially false negative results.

OBSERVATION 7

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically, there is no stability data to support the 180 expiration date assigned to all injectable drug products.

OBSERVATION 8

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

Specifically, injectable drug products are not tested for specifications using validated methods.

OBSERVATION 9

The labels of some of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and (B).

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Specifically, the following information is not found on some of your drug product labels:

• The address and phone number of the outsourcing facility.

Examples of drug product labels that do not contain this information include:
- o Vitachrom Injection, 10mL
- o Triamcinolone Acetonide 50mg/mL, 10mL sterile injection
- o Methylprednisolone Acetate 80mg/mL, 10mL sterile injection
- o Lipo B sterile injection, 10mL
- o Ketorolac Tromethamine 30mg/1mL, 300mg/10mL
- o Dexamethasone Acetate LA 8 mg/mL, 10 mL sterile injection
- o Tri-Mix 30/2/40 injection, 5mL
- o Tri-Mix 30/2/20 injection, 5mL
- o Tri-Mix 30/1/10 injection, 5mL
- o Bi-Mix 30/1 injection, 5mL

• The strength (of each active ingredient).

Examples of drug product labels that do not contain this information include:
- o Vitachrom Injection, 10mL

• The statements "This is a compounded drug" and "Not for resale."

Examples of drug product labels that do not contain this information is:
- o Flurbicaine
- o Keprocaine
- o Neurocaine

OBSERVATION 10

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the six

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months prior to registration as required by section 503B(b)(2)(A). Specifically, the following products were compounded and not identified on your submitted list on June 24, 2015:

- o Arthro-Infusion
- o Flurbicaine
- o Flurbi-Flex
- o Testosterone
- o Keta/Baclo/Gaba/Imp/Nifed/Tetra
- o Libido Cream
- o LibidoMax Cream
- o Keprocaine
- o Myo-Infusion
- o Kepro-Flex
- o Neurocaine
- o Plantar Flex
- o Shingleve
- o Woundheal
- o Progesterone

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*Dates of inspection: 8/3 - 7/2015, 8/11-12/2015, 8/14/2015, 8/18/2015, 8/20 - 21/2015

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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."