DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	03/18/2013 - 03/21/2013* FEI NUMBER 3001545640

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gene Ragazzo, RPh,, Co-Owner

FIRM NAME	STREET ADDRESS
Drugs Are Us, Inc. dba Hopewell Pharmacy	1 W Broad St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hopewell, NJ 08525-1901	Producer of Sterile Human 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

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

Specifically,

a. On 3/19/2013, plates for viable air monitoring were not observed in the incubator, although firm documentation showed that (b) (4) surface, glove fingertip, and viable air environmental monitoring plates had been collected on 3/14/2013 and were to be read on 3/20/2013. In addition, there is no assurance the media and incubation conditions can support growth.

b. Differential pressure is not monitored between the ISO 6 and ISO 7 areas; ISO 7 and ISO 8 areas; and ISO 8 and the uncontrolled office.

c. There is no assurance that the test to visualize unidirectional air flow and the collection of non-viable particle counts were performed under dynamic conditions, as stated in the most recent report dated 10/12/2012. This study was performed (b) (4) in the study.

d. There is no scientific rationale for the frequency of non-viable particle count collections in the ISO-5, ISO-6, and ISO-7 areas. Data is collected once every (b) (4)

Injectable products produced in the aseptic processing area include: Methylcobalamin 25mg/ml Injectable, Glycerin 72% (w/v) Injectable, Pyridoxine HCl 100mg/ml Injectable, and Trimix Injectable (Papaverine, Phentolamine, Prostaglandin E1 30mg/0.5mg/5mcg/ml).

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Karen E. D'Orazio, Investigator Nicholas A. Violand, Investigator	03/21/2013

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Gowning worn by personnel working in ISO-5 laminar flow hoods does not cover all skin, clothing, and shoes. Gowning consists of a three-quarter length sterile disposable coat, bouffant cap, shoe covers, face mask, and sterile gloves, as observed on 3/18/2013.

OBSERVATION 3

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

Specifically,

There is insufficient data demonstrating the chemical stability and sterility of injectable drug products throughout their beyond use dates. For example:

- Pyridoxine 100mg/ml Injectable is produced with a 6-month beyond use date
- Glycerin 72% (w/v) Injectable is produced with a 6-month beyond use date
- Methylcobalamin 25mg/ml Injectable is produced with a 3-month beyond use date
- Trimix Injection (Papaverine, Phentolamine, and Prostaglandin E1 30mg/0.5mg/5mcg/ml) is produced with a 2-month beyond use date

*** DATES OF INSPECTION:**
03/18/2013(Mon), 03/19/2013(Tue), 03/21/2013(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Karen E. D'Orazio, Investigator Nicholas A. Violand, Investigator	03/21/2013

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."