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	08/05/2013 - 08/19/2013* FEI NUMBER 3003348498

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Scott Karolchyk, R.Ph., MS, Co-owner

FIRM NAME	STREET ADDRESS
Pharmacy Creations	540 Route Ten West
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Randolph, NJ 07869	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

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

Specifically, there is a lack of potency and sterility assurance for non-preserved sterile preparations in that beyond use dates, up to 6 months, are assigned without supporting testing and the container closure integrity of the bottles and stoppers has not been established. Examples of products include: Epinephrine-Lyo (1mg/mL), lot 031913Y; Hyaluronidase NP (150 Units/mL) Sterile, lot 031313W; and Ropivacaine HCl Injection 0.2%, lot 0212642.

OBSERVATION 2

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

Specifically, media fill simulations are not representative of the preparation of aseptically filled sterile products. For example, the sterile preparation of Epinephrine-Lyo (1mg/mL), a lyophilized product, has several steps including (b) (4) (b) (4); however, the media fill simulation is limited to filling (b) (4) vials with media to assess the operator's aseptic technique.

OBSERVATION 3

Drug product containers were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically, the firm's method of removing pyrogens from glass vials and bottles consists of (b) (4); however, studies have not been conducted to demonstrate this method can reduce pyrogens to acceptable levels.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Douglas C. Kovacs, Investigator Michael R. Klapal, Investigator	08/19/2013

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OBSERVATION 4

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

Specifically, sterility testing of batches consisting of less than [redacted] vials is conducted in-house using [redacted] methods; however, positive and negative controls are not run to demonstrate the validity of the test and the methods have not shown been to be adequate. Additionally, potency is not routinely tested for any of the products and endotoxin testing is not performed on batches of [redacted] vials or less.

OBSERVATION 5

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

Specifically, non-viable particulate monitoring is limited to [redacted] during the certification of the [redacted]. There is no periodic monitoring of non-viable particulates during the aseptic fill process of batches that may include up to [redacted] units.

* DATES OF INSPECTION:
08/05/2013(Mon), 08/06/2013(Tue), 08/07/2013(Wed), 08/19/2013(Mon)

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	Douglas C. Kovacs, Investigator Michael R. Klapal, Investigator	08/19/2013