DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	5/24/2016-6/10/2016* FEI NUMBER 3005471681

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Charles A. Fulmer, RPh. , Owner	
FIRM NAME	**STREET ADDRESS**
Partners In Care, Inc.	2551 Limestone Pkwy, Suite 2
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Gainesville, GA 30501	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

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

Specifically,

A. There is no stability data to support the expiration or beyond-use-dates assigned to some of your sterile drug products. In addition, your firm was unable to provide any documentation that would scientifically justify the extended beyond-use-dates assigned to these sterile products.

1.) Gentamicin Irrigation 160 mcg/mL Solution; Assigned a beyond-use-date of 90 days.

2.) Papaverine 30 mg/mL Injectable; Assigned a beyond-use-date of 365 days.

3.) Triple Mix #4 30 mg, 2 mg, 20 mcg/mL Injectable; Assigned a beyond-use-date of 90 days.

4.) Cyanocobalamin 1000 mcg/mL Injectable; Assigned a beyond-use-date of 720 days.

5.) Edetate Disodium 1% Ophthalmic; Assigned a beyond-use-date of 90 days.

6.) Formalin Bladder 1% Solution; Assigned a beyond-use-date of 365 days.

7.) Testosterone Cypionate Oil 200 mg/mL Injectable; Assigned a beyond-use-date of 720 days.

B. The following products were assigned beyond-use-dates that surpassed that of one or more of the active pharmaceutical ingredients (APIs) or drug components.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rachael L. Cook Rachael L Cook, Investigator (CTNII) Tamara J Henderson, Investigator	X Rachael L Cook	DATE ISSUED 6/10/2016

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1.) Hydroxyprogesterone Caproate 250 mg/mL Injectable, Lot #20160509@10, beyond-use-date: 6/03/2017 was produced with the below component:

- (b) (4), Lot #(b) (4), beyond-use-date: 4/28/2017.

2.) Edetate Disodium 1% Ophthalmic, Lot #t20160414@5, beyond-use-date: 7/13/2016, was produced with the below component:

- (b) (4) Lot #20160414@8, beyond-use-date: 4/21/2016.

3.) T3 (Triiodol Thyronine) (b) (4), Lot #(b) (4), beyond-use-date: 4/03/2018, was produced with the below API and components:

a. Liothyronine (b) (4) (T3) (b) (4), Lot #(b) (4), beyond-use-date: 8/31/2016.
b. (b) (4), Lot #(b) (4), beyond-use-date: 11/30/2016.
c. (b) (4)), Lot #(b) (4), beyond-use-date: 5/21/2016.

4.) Triple Fish Suspension, Lot #20160229@19, beyond-use-date: 2/18/2018, was produced with the below components:

a. (b) (4) Lot #(b) (4), beyond-use-date: 9/11/2016.
b. (b) (4) Lot (b) (4), beyond-use-date: 3/31/2017.
c. (b) (4) Lot #(b) (4) beyond-use-date: 2/19/2017.

5.) Hydromorphone 3 mg Suppository, Lot #t20160225@6, beyond-use-date: 2/24/2017, was produced with the below API and component:

a. Hydromorphone (b) (4), Lot (b) (4), beyond-use-date: 1/31/2016.
b. (b) (4), Lot #(b) (4), beyond-use-date: 12/31/2016.

6.) Testosterone Cypionate Oil 200 mg/mL Injectable, Lot #20160209@1, beyond-use-date: 1/29/2018, was produced with the below APIs and components:

a. Testosterone Cypionate (b) (4), Lot (b) (4), beyond-use-date: 8/29/2016.
b. Testosterone Cypionate (b) (4), Lot #(b) (4), beyond-use-date: 5/28/2017.
c. (b) (4) Lot #(b) (4) beyond-use-date: 4/30/2017.
d. (b) (4), Lot # (b) (4), beyond-use-date: 10/31/2016.

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,

A. Your firm uses (b) (4). (b) (4) (b) (4) at (b) (4) of (b) (4) to sterilize some of your drug products including Hydroxyprogesterone Caproate 250 mg/mL Injectable Lot 20160509@10. However, the (b) (4) (b) (4) were not validated to demonstrate that the process is capable of producing a sterile product.

B. The (b) (4) depyrogenation (b) (4) used to sterilize equipment utilized in the processing of sterile drug products has not been validated to demonstrate that the process is capable of achieving depyrogenation of glassware, ceramic ware, and metal equipment.

C. Your firm does not use (b) (4) to determine the efficacy of the (b) (4) sterilization

process you utilize to sterilize drug products.

D. Media fills are not performed by personnel who engage in sterile drug processing on a semi-annual or annual basis to ensure continued understanding and proficiency of the sterile drug process. Media fill training is only performed (b) (4) and is not representative of the types of products or the maximum batch sizes produced by the firm.

E. Your firm has not conducted smoke studies under static or dynamic conditions within the ISO-5 laminar flow hood to ensure that the presence of operators and equipment do not impede the laminar airflow from the HEPA filters.

OBSERVATION 3

There was a failure to handle and store closures at all times in a manner to prevent contamination.

Specifically,

Your firm does not document the number of times you puncture the stoppers of the multi-dose vials that contain (b) (4) which are used in the production of sterile drug products. You were unable to provide any scientific documentation of the relationship between the number of punctures and the beyond-use-dates to demonstrate that your (b) (4) in multi-dose vials have the quality that they are purported to possess.

OBSERVATION 4

Written procedures are lacking which describe in sufficient detail the approval and rejection of components.

Your firm does not have a procedure in place for the approval of components that are used to produce sterile drug products.

Specifically, your firm uses non-medical grade (b) (4) to produce the Prostaglandin Injectable that is used to aseptically produce Triple Mix Injectable.

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OBSERVATION 5

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

Specifically,

Viable and nonviable environmental air and surface sampling is not conducted during active aseptic drug production.

OBSERVATION 6

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

Specifically,

A. Your firm has failed to establish appropriate hold times following the sterilization of your equipment and utensils used during aseptic processing of your sterile drug products.

B. Sterile wipes are not used for the cleaning of the ISO 5 Laminar Flow Hood, which would prevent the transmission of particulates into the sterile products.

*DATES OF INSPECTION

5/24/2016(Tue),5/25/2016(Wed),5/26/2016(Thu),5/27/2016(Fri),5/31/2016(Tue),6/03/2016(Fri),6/09/2016(Thu),6/10/2016(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rachael L. Cook Rachael L Cook, Investigator (CTNH) Tamara J Henderson, Investigator	X Rachael L Cook Rachael L Cook Investigator (CTNH) Signed by: Rachael L. Cook -5	DATE ISSUED 6/10/2016