DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	6/3/2016-6/10/2016* FEI NUMBER 3011432609

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ms. Cheryl A. Estep , Co-owner	
FIRM NAME Precision Pharmacy Center, LLC	STREET ADDRESS 2903 Saturn St Ste A
CITY, STATE, ZIP CODE, COUNTRY Brea, CA 92821-6259	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy

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 OBSERVED:

OBSERVATION 1

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

Specifically, endotoxin testing is not performed for some of the sterile drug products. Furthermore, you do not have established specifications for endotoxin levels in finished sterile injectable drug products. For example:

- Hydroxyprogesterone caproate 280mg/ml oil solution Injectable was not tested for endotoxin levels. Also, no specification is set for endotoxin limits.
- Bimix (PAPV/Phent) 30mg/2mg per ml Injectable was tested for endotoxin ~~limits~~, but no specification is set for endotoxin limits.

DH 6/10/16

OBSERVATION 2

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

This is a repeat observation.

Specifically, the procedure for assigning beyond use dates (BUDs) does not specifically address the assignment of BUDs for sterile drug products. Furthermore, sterile drug preparations do not have complete data to support extended beyond use dates (BUDs). For example:

- Hydroxyprogesterone caproate 280mg/ml oil solution Injectable (containing the preservatives (b) (4) and (b) (4)) has a BUD of 60 days at ambient temperature. There is no

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	Djamila Harouaka, Generic Drug User Fee Amendments (GDUFA) 6/10/2016 X Djamila Harouaka Djamila Harouaka Generic Drug User Fee Amendments (GDUFA) Signed by: Djamila Harouaka -S (Affiliate)	6/10/2016

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data to support that drug potency is stable for 60 days.

- Trimix (PGE1/PAPV/Phent) contains the preservative (b) (4) and has a BUD of 45 days under refrigeration. There is only data to support potency up to 30 days, and sterility up to 40 days.

OBSERVATION 3

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

Specifically,

- differential pressure between the clean room and anteroom and between the anteroom and unclassified area are not continuously monitored.
- personnel monitoring is not performed every work shift.

***DATES OF INSPECTION**

6/03/2016(Fri),6/06/2016(Mon),6/10/2016(Fri)

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