OBSERVATION 1

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

Specifically,

(A) Environmental monitoring (EM) of the ISO 5 area is not performed each day that sterile drug products are produced.

(B) EM sampling on equipment which are touched and/or handled during sterile drug production is not performed. A pump is used during production of sterile drug products and to the ISO Class 5 hood during sterile drug production. The pump was not sampled as required by your EM program.

(C) Plates (Lot Exp. 3/29/2017) were used in EM on 5/30/2017.

(D) The temperature of the incubator used to incubate media fills, environmental monitoring surface samples, and samples is not monitored.

(E) Test procedures relative to appropriate laboratory testing for EM are not followed. Specifically, plates used to perform EM were not incubated at the correct temperature. During the inspection, all plates were incubated in the same incubator - the observed temperature on 6/5/2017 was C. Your SOP 300.10, states sample results are not documented for evaluation of overall control of the drug production environment.

(G) According to your SOP 300.10, sample results were not provided for the limit set.
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, the (b)(4) laminar airflow workstations did not cover the entire work surfaces. Consequently, there is no assurance that uninterrupted unidirectional laminar airflow is maintained during aseptic operations.

OBSERVATION 3
Cleaning pads or wipes used in the ISO 5 aseptic processing areas are not sterile.

OBSERVATION 4
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

(A) On multiple occasions during the aseptic processing of N-Butyl Alcohol 21% lnj (Lot # 06052017@35) on 6/6/2017, the pharmacist reached over unstoppered vials obstructing airflow in the ISO 5 (b)(4).

(B) On 6/6/2017, the pharmacist was observed unwrapping the aluminum foil over-wrap covering outside of the (b)(4), exposing the sterile unstoppered vials to lower than ISO 5 quality air.

OBSERVATION 5
The final container closures used for drug product intended to be sterile have not been de-pyrogenated.

Specifically, there is no rinsing or washing of the rubber stoppers conducted prior to the (b)(4).
OBSERVATION 6

Biological indicators were not used to verify the adequacy of the sterilization cycle.

Specifically, biological indicators were not used to verify the sterilization and depyrogenation of equipment, containers, and closures.

OBSERVATION 7

Each batch of drug product purporting to be sterile and (b)(4) is not laboratory tested to determine conformance to such requirements.

Specifically, the following sterile drug products were not tested for sterility and/or bacterial endotoxin prior to distribution:

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Lot #</th>
<th>Total Vials or Bottles Produced</th>
<th>Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic Acid (NC) 500 mg/mL Inj</td>
<td>(b)(4)</td>
<td>(b)</td>
<td>No sterility and endotoxin testing</td>
</tr>
<tr>
<td>Myers Cocktail Inj</td>
<td></td>
<td>(b)</td>
<td>No endotoxin testing</td>
</tr>
<tr>
<td>Progesterone 150 mg/mL Inj</td>
<td></td>
<td>(b)</td>
<td>No sterility and endotoxin testing</td>
</tr>
</tbody>
</table>

OBSERVATION 8

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, the assigned beyond-use dates are not supported by stability studies of actual product. Examples include but are not limited to:

<table>
<thead>
<tr>
<th>Drug Product</th>
<th>Beyond-Use Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Gluconate 1% Inj</td>
<td>180 days</td>
</tr>
<tr>
<td>Fluorescein 2% Ophthalmic</td>
<td>90 days</td>
</tr>
<tr>
<td>Gonadotropin (HCG) 500 U/mL Inj</td>
<td>45 days</td>
</tr>
<tr>
<td>Myers Cocktail</td>
<td>60 days</td>
</tr>
<tr>
<td>Quad-Mix (#3) 30/3/30/0.1 Inj</td>
<td>90 days</td>
</tr>
</tbody>
</table>
TO: Louis M. Micolucci, President/CEO

FIRM NAME: Boothwyn Pharmacy LLC

STREET ADDRESS: 221 Gale Lane

CITY, STATE AND ZIP CODE: Kennett Square, PA 19348

TYPE OF ESTABLISHMENT INSPECTED: Producer of sterile and non-sterile drug products

OBSERVATION 9
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, sufficient batch size was not used to simulate actual aseptic processing conditions to accurately assess the potential for contamination. The media fill test completed by the pharmacist on 5/26/2017 was performed with a media fill lot size of (b) (4) However, the batch size of the sterile drug product, Ascorbic Acid (NC) 500 mg/mL Inj (Lot # (b) (4) produced on 4/21/2017 was (b) (4)

OBSERVATION 10
The calibration of instruments is not done at suitable intervals in accordance with an established written program.

Specifically,
(A) No data was provided to support that the incubator used to incubate media fills, environmental monitoring surface samples, and gloved fingertip samples is qualified for its intended use. The incubator also has not been calibrated to ensure accuracy.
(B) The Magnehelic® differential pressure gauges used for monitoring pressure differentials between ISO classified rooms are not calibrated.
(C) There are no records to indicate the calibration of the (b) (4) ovens in the last five years of use since its installation in 2012. These ovens are used in the sterilization of finished drug products and depyrogenation of primary containers, glassware, and tools, such as scissors and forceps.
(D) There are no records to indicate the calibration of the (b) (4) in the last two years of use since its installation in 2015. These (b) (4) are used in the sterilization of finished drug products and primary container closures, such as rubber stoppers.