DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
900 US Customhouse, 200 Chestnut Street Philadelphia, PA 19106 Tel: (215)597-4390 Ext: 4200; Fax: (215)597-0875 Industry Information: www.fda.gov/oc/industry	06/05/2017 - 06/16/2017*
	FEI NUMBER 1000076625

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Louis M. Micolucci, President/CEO

FIRM NAME	STREET ADDRESS
Boothwyn Pharmacy LLC	221 Gale Lane
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Kennett Square, PA 19348	Producer of sterile and non-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 (I) (WE) OBSERVED:

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 (b) (4) pump is used during production of sterile drug products and (b) (4) to the ISO Class 5 hood during sterile drug production. The pump was not sampled as required by your EM program.

(C) (b) (4) plates (Lot (b) (4) ; Exp. 3/29/2017) were used in EM on 5/30/2017.

(D) The temperature of the incubator used to incubate medial fills, environmental monitoring surface samples, and (b) (4) samples is not monitored.

(E) Test procedures relative to appropriate laboratory testing for EM are not followed. Specifically, (b) (4) plates used to perform EM were not incubated at the correct temperature. During the inspection, all (b) plates were incubated in the same incubator - the observed temperature on 6/5/2017 was (b) C. Your SOP 300.10, (b) (4) " states ((b

(F) (b) (4) sample results are not documented for evaluation of overall control of the drug production environment.

(G) According to your SOP 300.10, (b) (4) . No justification was provided for the limit set.

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	Mindy Chou	Mindy M. Chou, Investigator	06/16/2017

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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) of the ISO 5 (b) (4) and ISO 5 (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% Inj (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 (b) (4) 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).

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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:

	Lot #	Total Vials or Bottles Produced	Testing
Ascorbic Acid (NC) 500 mg/mL Inj.	(b) (4)	(b	No sterility and endotoxin testing
Myers Cocktail Inj		(b	No endotoxin testing
Progesterone 150 mg/mL Inj		(b	No sterility and endotoxin testing

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:

	Beyond-Use Date
Calcium Gluconate 1% Inj	180 days
Fluorescein 2% Ophthalmic	90 days
Gonadotropin (HCG) 500 U/mL Inj	45 days
Myers Cocktail	60 days
Quad-Mix (#3) 30/3/30/0.1 Inj	90 days

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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 medial 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. This (b) (4) are used in the sterilization of finished drug products and primary container closures, such as rubber stoppers.

***DATES OF INSPECTION**

6/05/2017 (Mon), 6/06/2017 (Tue), 6/07/2017 (Wed), 6/08/2017 (Thu), 6/09/2017 (Fri), 6/13/2017 (Tue), 6/14/2017 (Wed), 6/15/2017 (Thu), 6/16/2017 (Fri)

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