DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, Nj 07054 Tel: (973) 331- 4900 Fax: (973) 331-4969	08/27, 28, 29, 30, 09/25 and 09/28/2018 FEI NUMBER 3005231215

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO:	
Mr. Thomas E. Silvonek, RPh, Owner	
FIRM NAME Dorneyville Pharmacy	STREET ADDRESS 3330 Hamilton Blvd
CITY, STATE AND ZIP CODE Allentown, PA 18103-4593	TYPE OF ESTABLISHMENT INSPECTED Producer of non-sterile and 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

The final containers/closures used for drug product intended to be sterile were not sterilized.

Specifically,

Finished product containers, closures, product contact beakers, and mixing rods which are treated for sterilization are wrapped in aluminum foil are stored in an ISO 7 room without an established hold time to ensure that these items remain sterile.

This observation is a repeated objectionable condition reported during the last inspection.

OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

a. The firm fails to use (b) (4) during the compounding of non-sterile drug products. For example, Potassium Bromide (VET) Oral 300 mg/mL solution, Buprenorphine 0.3 mg/mL liquid, and Dexamethasone 0.5 mg/mL oral rinse.

b. The firm has not conducted microbiological testing of the (b) (4) used in non-sterile production. This (b) (4) has been used as a component during the production of Potassium Bromide (VET) Oral 300 mg/mL solution, Buprenorphine 0.3 mg/mL liquid, and Dexamethasone 0.5 mg/mL oral rinse.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Jose M. Cayuela	Jose M. Cayuela, Consumer Safety Officer	09/28/2018