

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 11/5-8/18
	FEI NUMBER 3014538927

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Ms. Paula H. Grahmann, Pharm D., owner and Pharmacist in Charge

FIRM NAME Hallettsville Pharmacy, LLC	STREET ADDRESS 304 North Texana Street
CITY, STATE AND ZIP CODE Hallettsville, TX 77964	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-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 I (WE) OBSERVED:

**OBSERVATION #1**

Your firm produced highly potent drugs without providing adequate cleaning of work surfaces and utensils to prevent cross-contamination.

Specifically,

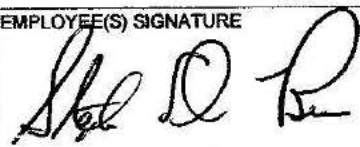
A. (b) (4) drug products including Testosterone and Estriol are produced under a (b) (4) hood. Your procedures document that (b) (4) is used to clean the work surface in the hood between preparations. Your firm has no evidence to show that the use of (b) (4) will effectively remove residues which might be present on the hood surface after production.

B. Your firm uses household dish liquid detergent and potable water for the cleaning of utensils such as rubber spatulas used in the processing of highly potent drug substances such as Estriol or Progesterone. All utensils are then washed in a dishwasher before subsequent use. I noted that several rubber spatulas used to transfer product were heavily stained.

Your firm has no evidence to show that your cleaning procedures can adequately remove residual drug products or detergent.

**OBSERVATION #2**

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products. For example, your firm uses (b) (4) water in specific formulations requiring water. The (b) (4) water is also used to produce (b) (4) Water which contains (b) (4). Your firm has no testing data to demonstrate that the (b) (4) Water meets, minimally, the specifications for Purified Water USP. Some examples of drug

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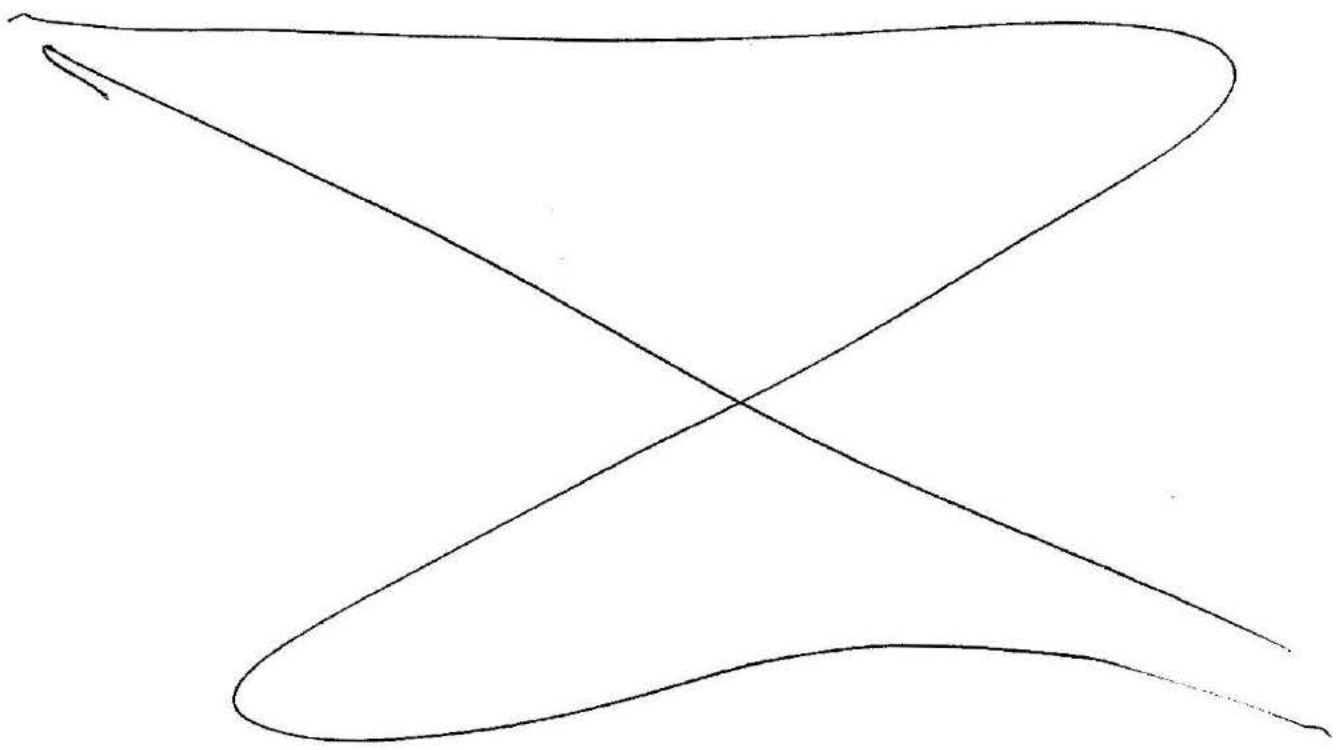
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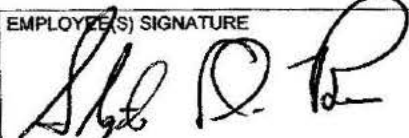
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products which used (b) (4) Water include the following:

A. Lidocaine 10/Prilocaine 10/Tetracaine 10/Phenylephrine 2%, lot #22983 was used with Rx #(b) (6) dated 9/21/18

B. Lidocaine 10/Prilocaine 10/Tetracaine 10/Phenylephrine 2%, lot #22867 was used with Rx #(b) (6) dated 8/27/18



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