

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	DATE(S) OF INSPECTION 2/9/2016-3/1/2016*
	FEI NUMBER 3004613997

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Howard L. Anthony , Owner

FIRM NAME Walter's Pharmacy	STREET ADDRESS 401 N 17th St
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CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18104-5034	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs
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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:
The following observations are applicable to ophthalmic and aqueous solution for oral inhalation products produced by your pharmacy.

These products are required to be sterile.

They include the following:

Ophthalmic Products

- Cefazolin Ophthalmic Solutions
- Tobramycin Ophthalmic Solutions
- Vancomycin Ophthalmic Solutions
- Voriconazole Ophthalmic Solutions
- Atropine Ophthalmic Solutions
- Silver Nitrate Ophthalmic Solutions
- Edetate DiSodium (EDTA) Ophthalmic Solutions
- Rose Bengal Ophthalmic Solutions

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE James M Mason, Investigator	<input checked="" type="checkbox"/> James M Mason <small>James M Mason Investigator Signed by: James M. Mason -S</small>	DATE ISSUED 3/1/2016

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Aqueous Solution for Oral Inhalation Products

Lidocaine Nebulizer Solutions

Additionally, two of the above products, Edetate DiSodium (EDTA) and Rose Bengal Ophthalmic Solutions, are produced from active ingredients that are non-sterile **(b) (4)**

OBSERVATION 1

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

All manipulations performed in the production of drug products required to be sterile are conducted in a non-sterile uncontrolled environment on the pharmacy counter.

Additionally, there is a sink located adjacent to the counter top where drug products are produced.

OBSERVATION 2

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

Employees performing manipulations in the production of drug products required to be sterile do not wear any sterile garb (gowns, hairnets, face masks, or sterile gloves) during production.

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Gloves are available to employees but they are not sterile and some employees do not wear any gloves while producing these products.

OBSERVATION 3

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

Specifically,

The beyond use dates (BUD) that you apply to sterile ophthalmic drug products are sometimes different than the dating cited in your references (i.e. (b) (4)).

The following are examples of differences between the beyond use dates of the reference (b) (4) to your actual beyond use date:

Cefazolin Ophthalmic Solution – Your product receives a 14 day beyond use date and your reference cites the product should receive a (b) (4) day beyond use date. Additionally, the (b) (4) that the product should receive a (b) (4) day beyond use date after reconstitution.

Tobramycin Ophthalmic Solution – Your product receives a 30 day beyond use date and your reference cites the product should receive a (b) (4) day beyond use date.

Voriconazole Ophthalmic Solution – Your product receives a 30 day beyond use date and your reference cites the product should receive a (b) (4) day beyond use date. Additionally, a second reference cited the product should receive a (b) (4) day beyond use date.

Silver Nitrate Ophthalmic Solution - Your product receives a 90 day beyond use date and your reference cites the product should receive a (b) (4) day beyond use date.

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Edetate DiSodium (EDTA) Ophthalmic Solution - Your product receives a 90 day beyond use date and your reference cites the product should receive a (b) (4) day beyond use date.

Additionally, your reference formulations are often different from how you actually make the product. The following is a summary of the ways in which your product formulations are different from the reference formulation:

Silver Nitrate Ophthalmic Solution – Your product uses (b) (4) while the reference product uses (b) (4).

Vancomycin Ophthalmic Solution – The reference formulation is (b) (4) while your formulation contains a preservative.

Cefazolin Ophthalmic Solution – Your formula uses (b) (4) in place of the reference formula's use of (b) (4).

Tobramycin Ophthalmic Solution – Your product contains a preservative while the reference formulation is (b) (4). Your product is (b) (4) while the reference formula uses (b) (4).

Atropine Ophthalmic Solution – Your product uses (b) (4) while the reference formulation uses (b) (4). Also, the strength of your product is 0.1% while the reference formulation is (b) (4).

Edetate DiSodium (EDTA) – The strength of your product is 2% while the reference formulation is (b) (4).

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Lidocaine Nebulizer Solution – The strength of your product is 1% or 2% while the reference formulation is (b) (4)

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

You have not established any written procedures regarding the production of drug products required to be sterile.

OBSERVATION 5

Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed.

Specifically,

The (b) (4) that is used as an ingredient in Methoxsalen topical drug products is labeled as being (b) (4) while USP grades of (b) (4) are commercially available.

***DATES OF INSPECTION**

2/09/2016(Tue),2/11/2016(Thu),2/17/2016(Wed),3/01/2016(Tue)

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