DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	12/14/2015-12/21/2015* FEI NUMBER 3011870779

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dwain C. Easley , Registered Pharmacist

FIRM NAME	STREET ADDRESS
Elkhart Pharmacy	306 US Hwy 287
CITY, STATE, ZIP CODE, COUNTRY Elkhart, TX 75839	TYPE ESTABLISHMENT INSPECTED Sterile Drug Producer

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

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

Your firm does not use a sporicidal agent or sterile wipes during the sanitation of the ISO-5 Laminar Airflow Hood, located in the ISO-7 classified sterile drug preparation room, where all sterile drug products are prepared. Your Standard Operating Procedure number 5.003, entitled, "Room Cleaning Procedures--Cleanroom", lacks provisions to ensure adequate use of sporicidal agents. The areas cleaned are the (b) (4) (b) (4) .

OBSERVATION 2

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

Specifically,

Your firm does not use, nor does it provide, sterile hair nets, sterile face masks, sterile beard nets, sterile eye wear, sterile gowns, or sterile boot covers for employees preparing sterile drug products.

OBSERVATION 3

Results of stability testing are not used in determining expiration dates .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Darla J Christopher, Investigator Jason R Caballero, Investigator 12/21/2015 X Darla J Christopher Darla J Christopher Investigator Signed by: Darla J. Christopher -S	12/21/2015

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Elkhart, TX 75839	Sterile Drug Producer

Specifically,
You send your products off for stability studies to an outside contractor, but you do not base your BUD dates upon the contractor's findings. You are currently giving an arbitrary six month BUD, regardless of the product. Your Standard Operating Procedure number 8.021.1, entitled, "Beyond Use Dating", is not specific to each sterile preparation.

OBSERVATION 4
Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

Your (b) (4) ISO-5 Laminar Airflow Hood in the sterile processing room was certified by your outside contractor on (b) (4), expiring on 07/31/2015. The LAF hood was not re-certified again until (b) (4). Your firm filled (b) (4) sterile drug products between 08/06/2015 and 08/19/2015 inside that LAF hood. Products compounded during that lapse were:

(b) (4)

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Elkhart, TX 75839	Sterile Drug Producer

*DATES OF INSPECTION

12/14/2015(Mon),12/15/2015(Tue),12/16/2015(Wed),12/18/2015(Fri),12/21/2015(Mon)

12/21/2015

X Jason R Caballero

Jason R Caballero
Investigator
Signed by: Jason R. Caballero -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."