

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry		06/17/2013 - 06/21/2013*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER
TO: Patricia Stephens, R.PH, Pharmacist in Charge/Owner		3009925820
FIRM NAME	STREET ADDRESS	
Medi-Fare Drug and Home Health Center	300 West Pine Street	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Blacksburg, SC 29702	Producer of 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 separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

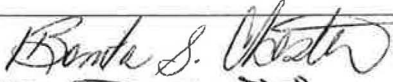
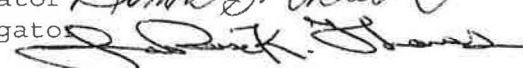
- A. The current design of your ISO 5 aseptic filling zone is inadequate in that the plexi-glass air foils surrounding the laminar air flow work benches, where sterile processing of drug product occurs, fail to prevent microbial contamination.
- B. Smoke pattern studies performed on 3/13/13 were not conducted under adequate conditions in that:
 1. The air flow is diffuse proximal to the work surface and not unidirectional.
 2. Gaps within the plexi-glass air foils allow the leakage of smoke into the aseptic processing area.
 3. Simulations were not performed under dynamic conditions that mimic actual production which could potentially impact the sterility of products produced such as:
 - a. Maximum personnel
 - b. Extended exposure times, interventions, and longer processing times
 - c. Maximum batch sizes
 - d. Lack of equipment and utensils routinely used in the conduct of sterile processing

OBSERVATION 2

Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically,

Sterile operations are being conducted by operators that wear non-sterile gowns in the aseptic processing area. In addition, your current procedures, SOP 05-04.01, "Sterile Hand Hygiene and Garbing Procedure", does not require the sampling of any parts of operator gowns at any determined frequency to ensure such gowns are appropriate for use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Bonita S Chester, Investigator  Lareese K. Thomas, Investigator 	06/21/2013

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CITY, STATE, ZIP CODE, COUNTRY Blacksburg, SC 29702	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs	

OBSERVATION 3

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

Specifically,

- A. Media fills do not simulate routine aseptic processing that incorporate worse case activities and conditions that may provide a challenge to aseptic operations (i.e. maximum batch sizes, maximum personnel, interventions, container/closure systems, etc.) Currently, media fills are only performed as a part of ongoing employee (b) (4) qualifications.
 1. Aseptic media fills were performed by sterile drug personnel on 1/28/13 and approved on 2/11/13. However, these media fills were inadequate in that the aseptic process was not challenged to reflect the broadest scope of possible manipulations that could occur.
 2. Current procedures do not indicate that factors such as number of personnel in the aseptic production area during sterile operations and drug product batch sizes are evaluation factors for media fills. Moreover, the media fills performed on 1/28/13 are not representative of actual sterile drug productions at the firm.
- B. No environmental monitoring occurred during (b) (4) processing of Mitomycin Bladder Irrigation 40mg/ml (lot# 2013052803; BUD 11/25/13) on 5/29/13. Surface sampling was performed and documented only on 5/31/13. Environmental sampling continues to occur (b) (4).
- C. Personnel monitoring is inadequate in that:
 1. No glove fingertip sampling was performed for either sterile drug operations performed to ensure that contamination of the drug products had not occurred. Fingertip sampling continues to be performed only during (b) (4).
 2. Current procedure, SOP 03-08.01, "Sterile Gloved Fingertip Sampling", requires only (b) (4) fingertip monitoring.
- D. Validation activities performed on the (b) (4) were inadequate in that:
 1. There is no formal written protocol describing the complete process used to conduct such validation and how the assessment of data therein is to be evaluated.
 2. Procedural design executed on 04/23/13 consisted of only using open vials containing biological indicators to support cycle parameters used in sterilization of product vials and or finished product.
 3. Heat distribution and penetration studies have not been evaluated with the use of thermocouples, sensors, and other appropriate monitoring devices to ensure that the (b) (4) will function within predetermined specifications to support cycle parameters currently established for the sterilization of equipment and finished products.

*** DATES OF INSPECTION:**

06/17/2013(Mon), 06/18/2013(Tue), 06/19/2013(Wed), 06/21/2013(Fri)

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