DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Atlanta District Office, 60 8th St NE, Atlanta, GA 30309 (404) 253-1161 Industry Information: www.fda.gov/oc/industry	09/09/14-09/12/14
	FEI NUMBER 3009925820

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patricia (nmi) Stephens, Pharmacist/President/Owner

FIRM NAME	STREET ADDRESS
Medi-Fare Drug and Home Health Center, Inc.	300 West Pine Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Blacksburg, SC 29702	Outsourcing Facility

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:

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

Specifically,

a) The firm currently utilizes (b) (4) to disinfect inside the ISO 5 Laminar Air Flow Work Benches (aseptic processing areas); nonetheless, these disinfecting agents are not sterile.

b) Disinfecting and sporicidal agents, including dilution, being utilized for aseptic processing areas have not been been selected based on a formal assessment as established in the written and approved standard operating procedure 4.010: Cleaning Program, effective 10/01/13. In addition, contact times need to be established.

2) The labeling of your outsourcing facility's drug products do not include information required by section 503B (a)(10).

Specifically,

(a) The drug product labels do not include the date that the drug was compounded (503B(a)(10)(A).

(b) The drug product containers do not include information to facilitate adverse event reporting and directions for use (503B(a)(10)(B).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Viviana Matta	Viviana Matta, Investigator Richard Lyght, Investigator	09/12/2014

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."