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 ORAPHARM2_RESPONSES@fda.hhs.gov	5/15/2023-5/26/2023* FEI NUMBER 3009925820

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anne Marie Davis, Quality Head

FIRM NAME	STREET ADDRESS
Medi-Fare Drug	300 W Pine St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Blacksburg, SC 29702-1548	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 OBSERVED:

Materials System

OBSERVATION 1

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, your firm has not performed any testing of components to ensure the reliability of the supplier's Certificate of Analysis.

OBSERVATION 2

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically, your firm does not conduct any identity testing of raw materials when received. In the last six months, your firm has compounded approximately (b) (4) separate lots that have been or are pending release.

Packaging and Labeling System

OBSERVATION 3

Samples of representative units were not visually examined for correct labeling at the completion of finishing operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jared P Stevens, Investigator	X Jared P Stevens Investigator Signed By: Jared P. Stevens -S Date Signed: 05-26-2023 11:12:28	5/26/2023

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Anne Marie Davis, Quality Head	
FIRM NAME Medi-Fare Drug	STREET ADDRESS 300 W Pine St
CITY, STATE, ZIP CODE, COUNTRY Blacksburg, SC 29702-1548	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically, two batches of Ephedrine Sulfate (25mg/5mL), were manufactured containing an erroneous NDC number on the label. Lot (b) (4), was distributed with the NDC (b) (4) instead of the correct NDC (b) (4)
Once aware of this complaint, your firm conducted an investigation which revealed that a second unreleased batch (Lot (b) (4)) contained the same incorrect NDC.

Facilities and Equipment System

OBSERVATION 4
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm utilizes (b) (4) that are not directly supplied with HEPA-filtered air and rely on a passive supply from a HEPA-filtered, ISO 7 room. This practice may allow introduction of contaminants from an unclassified space.

***DATES OF INSPECTION**
5/15/2023(Mon), 5/16/2023(Tue), 5/17/2023(Wed), 5/18/2023(Thu), 5/19/2023(Fri), 5/22/2023(Mon), 5/23/2023(Tue), 5/26/2023(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jared P Stevens, Investigator	X Jared P Stevens Investigator Signed By: Jared P. Stevens -S Date Signed: 05-26-2023 11:12:28	5/26/2023

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 judgment, 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."