

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

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202	DATE(S) OF INSPECTION 8/13/2018-8/17/2018*
	FEI NUMBER 3014461693

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David H. Jones, Pharmacy Manager

FIRM NAME HomeChoice Partners, Inc.	STREET ADDRESS 2848 Washington Rd
CITY, STATE, ZIP CODE, COUNTRY Augusta, GA 30909-2356	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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 equipment to produce aseptic conditions.

The equipment and cleaning practices used at your firm pose a risk to the sterility of the ISO 5 Laminar Flow Hood in which sterile drugs are produced. Specifically,

- a) Non-sterile gowns are used during the production of sterile drug products in the ISO 5 Laminar Flow Hood.
- b) The tubing connected to the stock solutions of (b) (4) (b) (4) located in the ISO 5 Laminar Flow Hood are not sanitized between the production of different sterile drug products. On 8/14/18, the Sterile Compounding Technician touched the tubing several times during the production of Ertapenem 500mg/NS 50ml Easypump and did not sanitize the tubing prior to producing a different drug product.
- c) Prior to cleaning, sterile wipes were introduced into the ISO-5 area for routine daily cleaning and some of the unused wipes were left for cleaning throughout the remainder of the day. While the wipes were moved for cleaning underneath, they remained open and exposed in the ISO-5 area prior, during, and following cleaning completion.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tamara J Henderson, Investigator Johnetta F Walters, Investigator	Johnetta F Walters Investigator Signed By: Johnetta F. Walters -S Date Signed: 08-17-2018 13:51:08 X	DATE ISSUED 8/17/2018

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

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202	DATE(S) OF INSPECTION 8/13/2018-8/17/2018*
	FEI NUMBER 3014461693

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David H. Jones, Pharmacy Manager

FIRM NAME HomeChoice Partners, Inc.	STREET ADDRESS 2848 Washington Rd
--	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Augusta, GA 30909-2356	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
--	---

OBSERVATION 2

Buildings used in the manufacture, processing, packing or holding of drug products are not free of infestation by rodents, birds insects, and other vermin.

While witnessing cleaning of the cleanroom, two live insects were observed inside the ante room beyond the line of demarcation. At the time, the Sterile Compounding Technician was cleaning the ante room in preparation for the day's activities. The Technician noticed the first insect and shifted her body to step on it while wearing full gowning garb. She also continued to mop. Shortly thereafter, and prior to completion of mopping, a live spider was observed crawling from the same corner near the negative pressure room.

***DATES OF INSPECTION**

8/13/2018(Mon), 8/14/2018(Tue), 8/15/2018(Wed), 8/17/2018(Fri)

Tamara J Henderson
Investigator
Signed By: Tamara Henderson -S
Date Signed: 08-17-2018 13:52:01
X

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tamara J Henderson, Investigator Johnetta F Walters, Investigator	<p align="right">Johnetta F Walters Investigator Signed By: Johnetta F. Walters -S Date Signed: 08-17-2018 13:51:06 <u>X</u></p>	DATE ISSUED 8/17/2018