

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 08/02/2021-08/09/2021 9 VF 8/9/21
	FEI NUMBER 3014461693

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Donald J. Fillbeck, VP of Pharmacy

FIRM NAME HomeChoice Partners dba BioScrip Infusion Services	STREET ADDRESS 1 Seventh St., Suite 107
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CITY, STATE AND ZIP CODE Augusta, GA 30901	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
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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:

OBSERVATION 1

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area [aseptic processing areas] are not sterile.

The equipment and cleaning practices used at your firm pose a risk to the sterility of the drug products produced. Specifically,

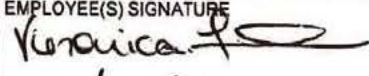

The (b) (4) wipes pack kept in the ISO 7 area has a (b) (4) and is not completely sealed. The remaining unused wipes were left in the pack in the ISO 7 environment and then used for sanitizing components and product going into the ISO 5 area. (REPEAT OBSERVATION)

OBSERVATION 2

The firm lacks smoke studies performed under dynamic conditions that mimic aseptic processing conditions. Specifically,

Multiple personnel were observed producing sterile drugs in the same hood simultaneously. However, the firm's smoke study video demonstrated that only one technician performed manipulations and interventions in one hood at a time.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE (Print or Type) Veronica Fuentes, Investigator Song Y. Lavalais, Investigator	DATE ISSUED 08/09/2021
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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."