

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

4040 North Central Expressway, Suite 300
Dallas, TX 75204
(214) 253-5300 Fax: (214) 253-5314

DATE(S) OF INSPECTION

7/25-28/2017; 8/2/2017

FEI NUMBER

3011074473

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Amy Groves, RN, MSN, Director of Operations

FIRM NAME

Option Care

STREET ADDRESS

9030 Kirby Drive

CITY, STATE AND ZIP CODE

Houston, TX 77054

TYPE OF ESTABLISHMENT INSPECTED

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 (I) (WE) OBSERVED:

OBSERVATION #1

Disinfecting agents used in the ISO 5 area are not sterile. Specifically, your firm utilizes (b) (4) disinfectants in the ISO 5 area (i.e. (b) (4)) which are not sterile.

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EMPLOYEE(S) SIGNATURE

Stephen D. Brown
Sha'Tina R. Alridge

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Stephen D. Brown, Investigator
Sha'Tina R. Alridge, Investigator

DATE ISSUED

08/02/2017