

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

19701 Fairchild
Irvine, CA 92612
(949) 608-2900

DATE(S) OF INSPECTION

07/31/2017-08/09/2017

FEI NUMBER

3013675130

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Susan M. Miller, Owner (Pharmacist)

FIRM NAME

D&S Enterprises, LLC dba Miller's Health Mart Pharmacy

STREET ADDRESS

777 37th, Suite C-100

CITY, STATE AND ZIP CODE

Vero Beach, FL

TYPE OF ESTABLISHMENT INSPECTED

Sterile Drug Producer

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

Your Pharmacy is producing sterile drugs in Compounding Aseptic Isolator (CAI) that is located in an unclassified buffer room. In addition, injectable sterile products are assigned a BUD of greater than 12 hours. For example, your pharmacy produced approximately a total of combined ^{(b) (4)} Morphine and Hydrocodone prescriptions for the year 2016 that were assigned a BUD of 48 hours at room temperature and 14 days in the refrigerator.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Sangeeta M. Khurana
[Signature]

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

SANGEETA M. KHURANA (CSO)
Santos Enrique Camara (CSO)

DATE ISSUED

08/09/2017