

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  19701 Fairchild Irvine, CA 92612 (949) 608-2900  Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION <b>07/31/2017-08/09/2017</b>
	FEI NUMBER <b>3013675130</b>

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Susan M. Miller, Owner (Pharmacist)**

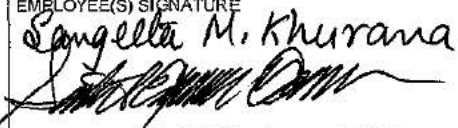
FIRM NAME <b>D&amp;S Enterprises, LLC dba Miller's Health Mart Pharmacy</b>	STREET ADDRESS <b>777 37th, Suite C-100</b>
CITY, STATE AND ZIP CODE <b>Vero Beach, FL</b>	TYPE OF ESTABLISHMENT INSPECTED <b>Sterile Drug Producer</b>

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 <sup>(b) (4)</sup> 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 	EMPLOYEE(S) NAME AND TITLE (Print or Type) <b>SANGEETA M. KHURANA (CSO)</b> <b>Santos Enrique Camara (CSO)</b>	DATE ISSUED <b>08/09/2017</b>
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