


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314		DATE(S) OF INSPECTION 5/14/2018-7/27/2018* FEI NUMBER 3013329127
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED John C. Davidson, Quality Director		
FIRM NAME Medcraft LLC	STREET ADDRESS 1312 Commercial Ave.	
CITY, STATE, ZIP CODE, COUNTRY Mounds, OK 74047	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility	
<p>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.</p>		
<p><b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b> <b>OBSERVATION 1</b></p> <p>Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.</p> <p>Specifically, your firm is not meeting the contact (dwell) times required by your procedure SOP-013 <u>Cleaning and Disinfection of the Facility</u>, version 3 effective January 11, 2017. Your procedure requires you to follow the contact times recommended by the manufacturer of the disinfectant. The labeling on the (b) (4) requires a (b) (4)-minute contact time for use as a sporicide and the (b) (4) requires a (b) (4)-minute contact time for use as a disinfectant. Your Pharmacist stated that he sprays the solution onto a sterile wipe and then wipes down the surface of the ISO 5 hood. The surface of the hood does not remain wet for the required (b) (4) or (b) (4)-minutes.</p>		
<p><b>*DATES OF INSPECTION</b> 5/14/2018(Mon), 5/15/2018(Tue), 5/16/2018(Wed), 5/17/2018(Thu), 7/24/2018(Tue), 7/27/2018(Fri)</p>		
<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Margaret M Annes, CSO	DATE ISSUED 7/27/2018
	 <p>Margaret M. Annes CSO Signed By: Margaret M. Annes, CSO Date Signed: 07/27/2018 10:15:21</p>	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
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