FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

January 30, 2019

VIA USPS PRIORITY MAIL

John C. Davidson, Quality Director
Medcraft, LLC
P.O. Box 317
Mounds, Oklahoma 74047

Mr. Davidson:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Medcraft, LLC, located at 1312 Commercial Ave., Mounds, Oklahoma 74047, from May 14, 2018, to July 27, 2018, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact H.L. Jamillah Selby, Compliance Officer, at 214-253-5218.

Sincerely,

John W. Diehl -S3

Digitally signed by John W. Diehl -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S3, 0.9.2342.19200300.100.1.1=2000099727
Date: 2019.01.30 11:29:22 -06'00'

CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

Enclosure: EIR

U.S. Food & Drug Administration
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