



Food and Drug Administration
Division of Pharmaceutical Quality
Operations IV
19701 Fairchild, Irvine, CA 92612
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October 18, 2018

Ms. Robin Smith Hoke
President/CEO
Denver Solutions, LLC dba Leiter's Health
13796 Compark Blvd
Englewood, CO 80112

Dear Ms. Hoke:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Denver Solutions, LLC dba Leiter's Health, located at 13796 Compark Blvd, Englewood, CO 80112, from February 12, 2018 to February 23, 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 Matthew R. Dionne, Pharm.D., Compliance Officer at 303-236-3064.

Sincerely,

**Matthew R.
Dionne -S**

Matthew R. Dionne, Pharm.D.
Compliance Officer, OPQO IV

Digitally signed by Matthew R. Dionne -S
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ou=People, 0.9.2342.19200300.100.1.1=1300425033,
cn=Matthew R. Dionne -S
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Enclosure: EIR