



August 6, 2019

Ashley Downing

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Dear Mrs. Downing:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your former facility, Downing Labs, LLC, located at 4001 McEwan Road, Suite 110, Dallas, Texas 75244, from September 17, 2018, to November 19, 2018, by the U.S. Food and Drug Administration (FDA). You were the co-owner of Downing Labs, LLC, at the time of the inspection and the EIR concerns your firm's status during your tenure.

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 me at 214-253-5288 or via e-mail at John.Diehl@fda.hhs.gov.

Sincerely,

Thao X. Ta

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Digitally signed by Thao X. Ta -S
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ou=HHS, ou=FDA, ou=People,
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For CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division 2

Enclosure: EIR

U.S. Food & Drug Administration
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