



November 16, 2020

VIA ELECTRONIC MAIL

Dr. Spencer J. Malkin
President and Chief Executive Officer
Sincerus Florida, LLC
3265 West McNab Road
Pompano Beach, Florida 33069

Dr. Malkin:

In separate electronic communication, we will be providing a copy of the Establishment Inspection Reports (EIRs) for the inspections conducted at your facility, Sincerus Florida, LLC, located at 3265 West McNab Road, Pompano Beach, FL 33069, from June 19, 2017, through June 26, 2017, and from August 30, 2018, through September 17, 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 these EIRs to you is part of this effort. The copies being provided to you comprises the narrative portion of the reports; 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 you have questions regarding the contents of this letter, you may contact Dayna Martinez Compliance Officer via phone at 787-729-8608 or email at dayna.martinez@fda.hhs.gov

Sincerely,

Digitally signed by John W Diehl 54
DN: c US o U.S. Government ou HHS
ou FDA ou People cn John W Diehl 54
0 9 2342 19200300 100 1 1 2000099727
Date: 2020.11.16 15:01:26 -06:00

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

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
1201 Main Street, Suite 7200
Dallas, Texas 75202
www.fda.gov