



April 24, 2019

CMS #: 574031

VIA UPS EXPRESS

Rene F. Garza, PharmD
Chief Executive Officer
Stonegate Pharmacy LP
2501 W. William Cannon Drive, Suite 203
Austin, Texas 78745

Dr. Garza:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Stonegate Pharmacy LP, located at 2501 W. William Cannon Drive, Suite 203, Austin, Texas 78745, from May 30, 2018, to June 11, 2018, and the EIR for the inspection conducted from February 23, 2016 to March 2, 2016, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing a letter sent to the Texas State Board of Pharmacy for follow up.

When the Agency considers an inspection to be “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 Jose R. Lopez, Compliance Officer, at (787) 729-8603, or by email at JoseR.Lopez@fda.hhs.gov.

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

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