

3/14/2019

CMS Case # 524736

VIA UPS EXPRESS

Ernesto Garza Gongora, PharmD - Owner Stone Oak Pharmacy 18866 Stone Oak Parkway Suite 101 San Antonio, TX 78258

Dear Dr. Garza Gongora:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Stone Oak Pharmacy, located at 18866 Stone Oak Parkway Suite 101, San Antonio, TX 78258, from November 28, 2016, to December 6, 2016, 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. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

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 Shawn Larson at Shawn.Larson@FDA.hhs.gov. For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Mark W. Rivero - S

Distally signed by Mark W. Rivero - S

DN: c=U.S. Government, ou=HHS, ou=FDA,
ou=People; cn=Mark W. Rivero - S,
0.9.234.219200300.100.1.1=1300060122
Date: 2019.03.1415.0550-0500°

Mark W. Rivero

Acting Director, Compliance Branch

Office of Pharmaceutical Quality Operations Division II

Enclosure: EIR

CC: Allison Vordenbaumen Benz - Executive Director Texas State Board of Pharmacy William P. Hobby Building, Suite 3-500

333 Guadalupe Street

Austin, TX 78701

U.S. Food & Drug Administration Office of Pharmaceutical Quality Operations, Division II 4040 N. Central Expressway, Suite 300 Dallas, Texas 75204 www.fda.gov