



May 8, 2018

UPS Overnight

James G. Castillo, President
Tiberius, Inc.
27732 Cashford Circle
Wesley Chapel, FL 33544

Dear Mr. Castillo:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Tiberius, Inc., located at 27732 Cashford Circle, Wesley Chapel, FL 33544, from May 15, 2017, to May 18, 2017, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Florida 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 and we have enclosed a copy with this letter.

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 Lopez, Compliance Officer, at 787-729-8603.

Sincerely,

John W. Diehl Digitally signed by John W. Diehl -S
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ou=FDA, ou=People, cn=John W. Diehl -S,
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Date: 2018.05.08 12:35:52 -05'00

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