DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200 – Suite 500
Nashville, TN 37217

Telephone: (615) 366-7801
FAX: (615) 366-7802

May 27, 2016

Enrique DuBois, Sr., President/Owner
Transdermal Therapeutics, Inc.
211 Summit Parkway, Suite 124
Birmingham, AL 35209

Location: Transdermal Therapeutics, Inc.
211 Summit Parkway
Birmingham, AL 35209

Dear Mr. DuBois, Sr.:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Transdermal Therapeutics, Inc., located at 211 Summit Parkway, Suite 124, Birmingham, Alabama, from June 23 - 27, 2014, 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.

Although the Agency has concluded that this inspection is "closed," we reiterate our observations noted on the Form FDA 483 issued to your firm on June 27, 2014, that your firm's procedures regarding investigation of consumer complaints appear inadequate. Specifically, your firm's written procedures for handling complaints do not include provisions for a full review or investigation, and do not allow for review to determine if the complaint represents serious and unexpected adverse drug experiences to help prevent future quality problems with drug products made by your firm. To date, we have not received notification of any corrective actions your firm may have taken to correct these concerns.

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.

This letter is not intended as an endorsement or certification of your facility. It remains your responsibility to ensure compliance with the requirements of federal law, including FDA regulations.

If there is any question about the released information, you may contact Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Thomas D. Clarida

Thomas D. Clarida
Acting District Director
New Orleans District

FEI 3010813678
Enclosure: Establishment Inspection Report (EIR)