

TO: US FDA New Orleans District (NOL-DO)
ATTN: New Orleans District Director, NOL-DO
C. Minden, Investigator, NOL-DO
404 BNA Drive, Bldg. 200 - Ste. 500
Nashville, TN 37214

Re: Posting of FDA Form 483 Response

FEI: 3010813678, Transdermal Therapeutics, Inc.

EI: 06/23/2014 - 06/27/2014

Dear Sir/Madam,

Please accept this letter as authorization to post on the US FDA Internet website Transdermal Therapeutics, Inc.'s response to the FDA Form 483 Notice of Observations, dated 09/23/2014, as submitted to NOL-DO, unredacted but without attachments. We understand this response will be posted under the FDA Form 483 Notice of Observations for Transdermal Therapeutics, Inc., issued on 06/27/2014 by Investigator Minden (NOL-DO).

Thank you,



Enrique Dubois, President

Transdermal Therapeutics, Inc.

211 Summit Parkway, Suite 124

Birmingham, AL 35209

Tel: 877-581-5444



211 Summit Parkway, Suite 124
Birmingham, AL 35209
September 23, 2014

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OCT 14 2014

NOL-DO Compliance Branch

PRIVATE AND CONFIDENTIAL

VIA U.S. MAIL

Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, Tennessee 37217-2597

Re: Transdermal Therapeutics, Inc.

Dear Sir or Madam:

I previously wrote to you on behalf of Transdermal Therapeutics, Inc. ("Pharmacy"), which received a FDA Form 483 ("483") issued to the Pharmacy by Claire M. Minden (the "Investigator") on June 27, 2014. In my first letter (the "Objection Letter"), I explained that the Pharmacy is a retail pharmacy that operates under the pharmacy compounding exemption found in Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and thus the Pharmacy is not required to comply with the Current Good Manufacturing Practices for Finished Pharmaceuticals ("cGMP") on which the observations in the 483 were based.

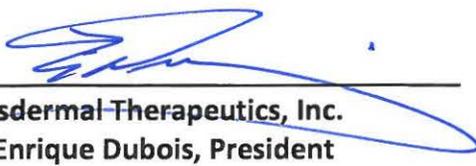
I also requested, should the FDA choose to publish the 483 issued to the Pharmacy, that the Objection Letter explaining the Pharmacy's response to the observations in the 483 be published, as well. It has come to our attention that the 483 is now available on the FDA's website. To date, the Objection Letter has not been published.

We respectfully renew our request that you publish the Objection Letter, as well as this letter, along with the publicly available 483. I am enclosing a copy of the Objection Letter for your convenience. As stated in the Objection Letter, the negative consequences that can flow from the FDA's publication of the 483, even if no further action is taken regarding the observations therein, require that the Pharmacy's response and objections also be publicly acknowledged.

We look forward to receiving confirmation that the FDA has published the Objection Letter and this letter along with the 483 issued to the Pharmacy. Too, we renew our assertion that the Pharmacy is, and continues to be, entitled to operate under the FDCA 503A exemption and not under any of the cGMP's listed in the 483.

Please do not hesitate to contact me should you have any questions or concerns regarding this matter.

Sincerely,



Transdermal-Therapeutics, Inc.
By: Enrique Dubois, President

**cc: Susan Alverson, Pharm.D.,
Executive Secretary,
Alabama Board of Pharmacy**

**J. Birch Bowdre, Esq.
William B. Stewart, Esq.**



211 Summit Parkway, Suite 124
Birmingham, Alabama 35209
877-581-5444 Fax: 877-495-5445
July 8, 2014

PRIVATE AND CONFIDENTIAL

VIA U.S. MAIL

Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, Tennessee 37217-2597

Re: Transdermal Therapeutics, Inc.

Dear Sir or Madam:

Transdermal Therapeutics, Inc. ("Pharmacy") is in receipt of the FDA Form 483 ("483") issued to the Pharmacy by Claire M. Minden (the "Investigator") on June 27, 2014. The 483 includes eight (8) observations that the Investigator made during the course of a five (5) day inspection. After review of the 483, and consultation with our legal counsel, we believe that all of the observations are based on regulations that are inapplicable to the Pharmacy.

The Pharmacy is a retail pharmacy that compounds medications for individual patients pursuant to physician prescription. The 483 designates the Pharmacy as a "Drug Product Producer," but we cannot find this term in any applicable statute or regulation and are unclear of its significance. As a compounding pharmacy, the Pharmacy is licensed by and complies with the rules and regulations promulgated by the Alabama Board of Pharmacy. Since it opened in 2010, the Pharmacy has operated under the pharmacy compounding exemptions in section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA").

The observations of the Investigator all appear to be based on Current Good Manufacturing Practices for Finished Pharmaceuticals ("cGMP") located at 21 C.F.R. Part 211. As a compounding pharmacy under the exemptions in section 503A, the Pharmacy is not subject to the cGMP. Instead, the Pharmacy is subject to (in addition to applicable state laws and regulations) Section 795 of the U.S. Pharmacopeia ("USP"), which establishes standards for non-sterile preparations of compounded pharmaceuticals. None of the observations in the 483 identify noncompliance with USP 795.

Even the Guidance released just last week by your Agency on "Pharmacy Compounding of Human Drug Products under Section 503A of the Federal Food, Drug and Cosmetic Act" states specifically, "A drug product intended for use in humans that is compounded in compliance with section 503A and its associated regulations is exempt from the requirements in sections 501(a)(2)(B), 502(f)(1) and 505 of the FD&C Act." Section 501(a)(2)(B) referenced in your Guidance is the section "concerning current good manufacturing practice." Those practices apply to drug manufacturers and companies that elect to register as an outsourcing facility, but do not apply to traditional compounders under 503A.

Is it possible that the Investigator inadvertently applied cGMP instead of the standards applicable to the Pharmacy? If not, we would appreciate more information supporting the reason why cGMP requirements were cited on the 483 as being applicable to compounders like the Pharmacy. We cooperated fully with the Investigator and interrupted the normal duties and activities of many of our key employees, including our Pharmacist-In-Charge, to supply the Investigator with everything requested. Several times during the week the Investigator commented that she had not seen anything in our operations that should cause the Pharmacy to be reclassified from its historical status as a compounding pharmacy under 503A. When the Investigator tendered the 483, we asked specifically why this notice was being supplied, and why the notice referenced regulations and practices that were inapplicable to a compounding pharmacy operating under 503A. We did not receive any substantive response or explanation.

We have consistently held our company out as a compounding pharmacy, not as a manufacturer (or an outsourcing facility). The Alabama Board of Pharmacy does not classify us as a manufacturer, but as a pharmacy. Since its inception, the Pharmacy has operated under the oversight and regulation of the Alabama Board of Pharmacy. We believe that the Pharmacy is entitled to continue to operate under the FDCA 503A exemption and that the cGMP cited are inapplicable to our operations.

In view of the substantial and negative consequences that can flow from your publication of the 483 issued to the Pharmacy (even if later withdrawn or resolved by agreement), we would request that you hold the 483 and not publish it on your website or any other publicly viewed forum until after a final determination is made regarding issues in the 483. If you choose to publish the 483 before then, we request that you attach a copy of this letter to any such publishing as we question the Agency's legal authority to apply drug manufacturing standards to an exempt compounding pharmacy.

We look forward to hearing from you regarding this matter.

Sincerely,



Enrique Dubois
President
Transdermal Therapeutics, Inc.

cc: Susan Alverson, Pharm.D.
Executive Secretary,
Alabama Board of Pharmacy

J. Birch Bowdre, Esq.
William B. Stewart, Esq.