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January 11, 2017

UNITED PARCEL SERVICE

Anthony Rubinaccio  
Executive Director  
New Jersey State Board of Pharmacy  
PO Box 45013  
Newark, NJ 07101

Dear Mr. Rubinaccio:

The purpose of this letter is to notify the New Jersey State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regard to an inspection at a pharmacy licensed by the New Jersey BOP, Plainsboro Pharmacy, located at 9 Schalks Crossing Road, Suite 712, Plainsboro, NJ 08536 (License # 28RS00662100).

FDA inspected the firm on July 30, 2014, after receipt of a MedWatch report dated July 17, 2014, regarding an adverse drug event experienced by a patient who received liothyronine (T3) sustained release (SR) capsules compounded by the firm. FDA analysis of a sample of the product found that it contained approximately 2.3 mg of liothyronine per capsule, which far exceeded the label claim. FDA investigators were accompanied by New Jersey State investigators. No Form FDA 483 was issued at the close of the inspection.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Plainsboro Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

FDA issued a warning letter to the firm on August 1, 2016, to address the super potency of the compounded liothyronine product. After review of the record and the firm's response to the warning letter<sup>1</sup>, it appears that the firm has addressed the violations contained in the warning letter. Plainsboro Pharmacy advised FDA that it "has ceased to fill all prescriptions containing the ingredient [liothyronine (T3)]" and changed its processes to ensure no further errors occur. FDA does not intend to take further action with regard to the findings of this inspection and

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<sup>1</sup> See attached the firm's response to the warning letter, dated August 2, 2016, from Yousry Macksoud, R.Ph., to the New Jersey District Office.

believes that the firm's pharmacy practice can be appropriately overseen by the State. We ask that you please follow up with Plainsboro Pharmacy to further assess the adequacy and sustainability of these corrections. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Liatte Krueger, Compliance Officer, at 1-973-331-4933.

Sincerely,

**Craig W. Swanson -S**

Digitally signed by Craig W. Swanson -S  
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Craig W. Swanson  
Acting District Director  
New Jersey District