



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
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May 29, 2020

VIA ELECTRONIC MAIL

Thai Huynh
Owner, Manager
Maryland Specialty and Compounding Pharmacy, LLC
(dba Professional Arts Pharmacy)
2015 Lord Baltimore Dr.
Windsor Mill, MD 21244-2558

FEI# 3004514280

Dear Mr. Huynh:

The U.S. Food and Drug Administration (FDA) has completed an evaluation of the corrective actions in response to our warning letter (WL # 518272) dated April 3, 2017. We acknowledge that your firm no longer produces sterile drug products. Based on our evaluation, it appears that you have adequately addressed the violations contained in this warning letter. We also note that Mr. Simeon Georgiou was the previous owner, but has since left the company.

You are expected to take all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations. If you decide to resume production of drug products intended to be sterile, FDA strongly recommends that you undertake a comprehensive assessment of your operations, including facility design, and that you notify FDA prior to resuming sterile production. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

If you have questions regarding the contents of this letter, please contact Juan Jiménez, Compliance Officer, by telephone at 518-453-2314 X-1014, or by email at Juan.Jimenez@fda.hhs.gov.

Sincerely,

Stephanie
T. Durso -S

Digitally signed by Stephanie T. Durso -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300194209,
cn=Stephanie T. Durso -S
Date: 2020.05.28 14:30:14 -04'00'

Stephanie Durso
Director Compliance Branch
U.S. Food and Drug Administration
OPQO Division I / New Jersey District

Office of Pharmaceutical Quality Operations

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