U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

DATE: September 28, 2022

VIA Electronic Mail
Return Confirmation Requested

Gary D. Daley, President
Randol Mill Pharmacy
1014 N. Fielder Rd.
Arlington, TX 76012-3149

Dear Mr. Daley:

The U.S. Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our warning letter (Case #610545) issued September 17, 2020. We acknowledge that your firm no longer produces sterile drug products as of November 2020. Based on our evaluation, it appears that you have adequately addressed the violations contained in this warning letter.

You are expected to take all necessary steps to ensure compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

Mark W. Rivero

Digitally signed by Mark W. Rivero
Date: 2022.09.28 08:07:01 -04'00'

Mark W. Rivero
Acting Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

U.S. Food and Drug Administration
Office of Pharmaceutical Quality Operations, Division II
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