



September 28, 2022

Tim Tucker, R.Ph., Pharm.D., Executive Director/Secretary
Texas Board of Pharmacy
George H. W. Bush State Office Building
1801 Congress Avenue
Suite 13100
Austin, Texas 78701

Ref: CMS WA #453861, FEI #3010177428

State Handoff Letter

Dear Dr. Tucker:

The purpose of this letter is to notify you, the Texas 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 of a pharmacy you licensed, Randol Mill Pharmacy, located at 1014 N. Fielder Road, Arlington, Texas 76012-3149.

FDA inspected the firm from May 16, 2022, to May 23, 2022. Your investigator accompanied FDA during part of the inspection.

No Form FDA 483 was issued to the firm. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the EIR that includes certain nonpublic information. You may also choose to request a copy of such documentation directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for drug products compounded by Randol Mill Pharmacy and FDA does not intend to take further actions at this time related to section 503A of the Federal Food, Drug, and Cosmetic Act. FDA believes that the firm's pharmacy practice can be appropriately overseen by the State. 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 Rebecca Asente,

U.S. Food & Drug Administration
Office of Regulatory Affairs
Office of Pharmaceutical Quality Operations, Division II
One Main Place, 1201 Main Street, Suite 7200
Dallas, Texas 75202
(214) 253-5200
www.fda.gov

Compliance Officer, at (504) 846-6104, or by email at Rebecca.asente@fda.hhs.gov.
Please use the reference numbers cited in the heading of the document.

Sincerely,

**Mark W.
Rivero**

 Digitally signed by Mark W.
Rivero
Date: 2022.09.28 08:10:14
-04'00'

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

Cc: Gary D. Daley, President
Randol Mills Pharmacy
1014 N. Fielder Road
Arlington, Texas 76012-3149