**May 19, 2020**

**Case #607992**

**VIA ELECTRONIC MAIL**

Tanja Battle
Executive Director
Georgia Department of Community Health
State Board of Pharmacy
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Ms. Battle:

The purpose of this letter is to refer to the Georgia State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about practices observed during an FDA inspection at a pharmacy licensed by the Georgia BOP, East Marietta Drug Company dba East Marietta Drugs, located at 1480 Roswell Road, Marietta, Georgia 30062-3670 (Retail pharmacy license: #PHRE007888; expires June 30, 2021).

FDA inspected the firm from August 19, 2019, to August 23, 2019. Georgia BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/131670/download, with any nonpublic information redacted. 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 you are a Commissioned Official or 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 Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by East Marietta Drug Company 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.

Additionally, during the inspection, the FDA investigators observed deviations from

appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm handles hazardous drugs with inadequate controls to prevent cross-contamination.
2. Non-microbial contamination was observed in production area.

East Marietta Drug Company committed to FDA in its response to the Form FDA 483, received September 13, 2019, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A of the Federal Food, Drug, and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Georgia State BOP for follow up to ensure appropriate corrective action is taken. 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 CDR John W. Diehl, M.S., Director, Compliance Branch, via phone at 214-253-5288 or e-mail at John.Diehl@fda.hhs.gov, or Thao Ta, Compliance Officer, via phone at 214-253-5217 or e-mail at Thao.Ta@fda.hhs.gov.

Sincerely,
John W. Diehl -S3

Digitally signed by John W. Diehl -S3
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S3, 0.9.2342.19200300.100.1.1=2000099727
Date: 2020.05.19 15:04:09 -05'00'

John W. Diehl
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

cc: VIA Electronic Mail

Jonathan Marquess, Co-Owner
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