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

November 5, 2019

Case #: WA 195914

VIA UPS OVERNIGHT

Susan McCoy
Executive Director, Mississippi Board of Pharmacy
6360 I-55 North, Suite 400
Jackson, Mississippi 39211

Dear Ms. McCoy:

The purpose of this letter is to inform the Mississippi Board of Pharmacy (BOP) of the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a facility, Coastal Meds, LLC, located at 1759 Medical Park Dr., Suite C, Biloxi, Mississippi 39532, registered with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b][1] on December 23, 2014, and most recently on October 27, 2017. The firm is no longer registered with FDA as an outsourcing facility. The facility was licensed by the Mississippi BOP as a Sterile Product Outsourcer (Facility Permit No. 14488; Expiration: December 31, 2019) and the status is currently classified as "closed" per the Mississippi BOP website.

FDA inspected the firm from March 12, 2018, to April 6, 2018. During the inspection, the investigator noted that drug products produced at the facility failed to meet the conditions of section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA. In addition, the investigator noted serious deficiencies in the facility's practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to the facility on April 6, 2018. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/112298/download, with any nonpublic information redacted. FDA received the facility's response to the Form FDA 483, dated April 26, 2018, in which the firm stated they decided to shut down its business, and had ceased all production and distribution of all sterile injectables, effective March 13, 2018. The firm further explained that they will close their business upon conclusion of their March 30,

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

2018, recall of all lots of unexpired sterile injectables distributed from October 25, 2017, to March 13, 2018.

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. As a Commissioned Official, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information.

FDA requests notification from the Mississippi BOP if the firm owner applies for licensure of a compounding facility in the state of Mississippi. Please notify FDA via the FDA address provided on the first page of this letter and via email to John.Diehl@fda.hhs.gov and ORAPHARM2_RESPONSES@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Rebecca A. Asente, Compliance Officer, via (504) 846-6104 or rebecca.asente@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: 2019.11.05 16:10:53 -06'00'

John W. Diehl, M.S
Director, Compliance Branch
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