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

March 10, 2021

Via Electronic Mail

Jessica Sapp
Executive Director
Florida Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, Florida 32399-3254

Ms. Sapp:

The purpose of this letter is to refer to the Florida 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 Florida BOP, Pacifico National, Inc. dba AmEx Pharmacy, located at 1515 Elizabeth Street, Suite J, Melbourne, FL 32901-3000 (Pharmacy License # PH16954).

FDA inspected the firm from April 15, 2019, to May 31, 2019. FDA investigators were accompanied by Florida state investigators for five days. A copy of a form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/128709/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.

In an email, received on September 24, 2019, the firm advised FDA of its intention to operate as a non-sterile pharmacy only.

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. Insanitary conditions observed during our inspection were primarily related to the firm's sterile operations, which have since been discontinued; however, some observations may be applicable to non-sterile production. Examples of deviations observed during our inspection include:

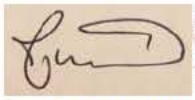
- The firm handled hazardous drug products without providing adequate cleaning and disinfection documentation for the prevention of cross-contamination.

AmEx Pharmacy committed to FDA in its response to the form FDA 483, received June 19, 2019, to correct the deviations in the form FDA 483 and provided documentation in support of those corrective actions. 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. Furthermore, this firm intends to produce only non-sterile drug products for individually identified patients before distributing its compounded drug products, as required by section 503A(a) of the FDCA. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Florida BOP for follow up to ensure appropriate corrective action is taken and to confirm that the firm has ceased sterile operations and is operating as a non-sterile pharmacy. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, if the firm has resumed sterile operations, 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 questions regarding the contents of this letter, you may contact Dr. Shawn Larson - Compliance Officer, via phone at 214-253-5216 or e-mail at Shawn.Larson@fda.hhs.gov.

Sincerely,



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

Cc: Mark L. Sangree, President
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