



April 22, 2019

CMS WA # 231749

Jennifer Wenhold, Executive Director
Florida State Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, Florida 32399-3254

Ms. Wenhold:

The purpose of this letter is to notify the Florida State 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 licensed by the Florida BOP, Pensacola Apothecary, Inc. dba Everwell Specialty Pharmacy, 6506 N Davis Highway, Pensacola, FL 32504-6957 (License #: PH19748).

FDA inspected the firm from August 2, 2018, to August 6, 2018. The Florida BOP was informed of the inspection but did not accompany FDA investigators during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Pensacola Apothecary, Inc. dba Everwell Specialty Pharmacy 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, which is consistent with traditional pharmacy practice. After review of the records, FDA does not intend to take further action with regard to the findings of this inspection at this time and 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.

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If you have additional questions, please contact Jose R. Lopez, Compliance Officer, at (787) 729-8603, or by email at JoseR.Lopez@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 -
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CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division II

Cc: Pensacola Apothecary, Inc. dba Everwell Specialty Pharmacy
6506 N. Davis Highway
Pensacola, Florida 32504-6957
