



August 19, 2019

Jack W. "Jay" Campbell IV, Executive Director
North Carolina State Board of Pharmacy
6015 Farrington Rd Suite 201
Chapel Hill, North Carolina 27517

Dear Mr. Campbell:

The purpose of this letter is to notify the North Carolina 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 North Carolina BOP, Aspirar Pharmacy, LLC located at 135 Parkway Office Court, Suite 105, Cary, North Carolina 27518-7425 (License #: 11629).

FDA inspected the firm from February 20, 2019, to February 27, 2019. Investigators from the North Carolina BOP accompanied FDA investigators during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Aspirar Pharmacy, LLC 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. If you have additional questions, please contact Mark W. Rivero, Compliance Officer, at (504) 846-6103, or mark.rivero@fda.hhs.gov.

Sincerely,

Thao X. Ta -S

Digitally signed by Thao X. Ta -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Thao X. Ta -S,
0.9.2342.19200300.100.1.1=1300068375
Date: 2019.08.16 15:29:32 -05'00'

For John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations
Division 2

Page 2 – Jack W. "Jay" Campbell IV, Executive Director
North Carolina State Board of Pharmacy
August 19, 2019

cc:
Aspirar Pharmacy, LLC
135 Parkway Office Court, Suite 105
Cary, NC 27518-7425
