July 12, 2017

Rodrick J. Marriott, Pharm.D.,
Director
Drug Control Division
Connecticut Department of Consumer Protection
450 Columbus Blvd, 901
Hartford, CT 06103

Dear Dr. Marriott:

The purpose of this letter is to refer to the Connecticut State Board of Pharmacy (BOP) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Connecticut BOP, Central Admixture Pharmacy Services Inc. (CAPS Connecticut) 27 Village Lane Wallingford, CT 06492 (Pharmacy-PCY0002066).

FDA inspected the firm from December 1, 2015, to January 29, 2016. FDA investigators were accompanied by Connecticut state investigators for approximately 3 days. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM489125.pdf, 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. 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 CAPS Connecticut 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. In the firm's response to the Form FDA 483, received February 24, 2016, CAPS Connecticut advised FDA that it "only compounds drugs for identified individual patients based on the receipt of valid prescriptions and also satisfies the other requirements of section 503A."

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting

U.S. Food and Drug Administration
Office of Regulatory Affairs
Division of Pharmaceutical Quality Operations 1
New Jersey District
10 Waterview Blvd. 3rd Floor
Parsippany, New Jersey 07054

patients at risk. We reviewed the CAPS Connecticut response to the Form FDA 483, received February 24, 2016, which included an in situ air pattern study. After review of the documentation provided, FDA expressed ongoing aseptic processing concerns at the CAPS Connecticut location. Specifically, the in situ air pattern video provided by CAPS demonstrated several discolored HEPA filters in the ISO 5 area. CAPS committed to correct the deviations. In addition to the observed HEPA filter discoloration, the firm lacked a pressure gauge to monitor the differential pressure between the ISO 8 area and the warehouse.

CAPS committed to FDA in its responses to the Form FDA 483, received February 24, 2016, and April 19, 2016, 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(a) 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 Connecticut 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 Maya Davis, Compliance Officer, at 860-240-4289 x25, or by email at maya.davis@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000 11579, cn=Diana Amador-toro -S
Date: 2017.07.12 15:38:33 -04'00'

Diana Amador-Toro,
Division Director/OPQ Division 1
New Jersey District Office

CC: Ms. Carol V. Dupont,
Director of Pharmacy
Central Admixture Pharmacy Services Inc.
27 Village Lane
Wallingford, CT 06492

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