



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
New England District
One Montvale Ave.
4th Floor
Stoneham, MA 02180

January 20, 2016

David Sencabaugh, R.Ph.
Executive Director
Massachusetts Board of Registration in Pharmacy
239 Causeway Street, 5th Floor, Suite 500
Boston, MA 02114

Dear Mr. Sencabaugh:

The purpose of this letter is to refer to the Massachusetts Board of Registration in Pharmacy (BORP) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor aseptic practices observed during an FDA inspection at a pharmacy licensed by the Massachusetts BORP, Merissa Corp., dba Johnson Compounding and Wellness Center, 577 Main St., Waltham, Massachusetts 02452-5527 (Pharmacy license numbers DS3579 and CS3579).

FDA inspected the firm from May 11, 2015, to May 28, 2015. The FDA investigator was accompanied by two Massachusetts state investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at:

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM451954.pdf>.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Johnson Compounding and Wellness Center 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 dispenses. In the firm's response to the Form FDA 483, received by FDA on June 19, 2015, the firm advised FDA that it "performs sterile and non-sterile compounding for preparation of a patient specific compounded medication pursuant to a patient specific prescription."

During the inspection, the FDA investigator observed deviations from appropriate aseptic practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm failed to demonstrate through appropriate studies that their hoods are able to provide adequate protection of the ISO 5 area in which sterile products are processed.

Specifically, the firm did not perform smoke studies under dynamic conditions representative of worst case processes to verify that there is no obstruction or alteration of laminar air flow that may contaminate the product.

2. Sterile wipes used for cleaning surfaces within ISO 5 areas were not stored in a manner that assures they remain sterile prior to use. Specifically, sterile wipes are opened and stored as such within the ISO 7 area for approximately one week.

Johnson Compounding and Wellness Center committed to FDA in its responses to the Form FDA 483, dated June 18, 2015, August 11, 2015, and August 31, 2015, to correct the deviations in the Form FDA 483.¹ In addition, the deviations identified appear to be readily correctable.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Massachusetts BORP 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 ex. 25, or by email at maya.davis@fda.hhs.gov.

Sincerely,

Joseph S.
Matrisciano
Jr -S

Digitally signed by Joseph S.
Matrisciano Jr -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
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Date: 2016.01.20 07:20:08 -05'00'

Joseph Matrisciano
Acting District Director
U.S. Food and Drug Administration
New England District Office

cc: William Frisch, Jr., R.Ph.
Director of Pharmacy Compliance
Massachusetts Board of Registration in Pharmacy
239 Causeway Street, 5th Floor, Suite 500
Boston, MA 02114

¹ Because you are an FDA commissioned official, you can request an unredacted copy of the Form FDA 483 or the firm's responses to the Form FDA 483, dated August 11, 2015, August 12, 2015, and August 31, 2015.