



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue, 4th Floor
Stoneham, MA 02180-3500

October 14, 2015

Monica Bharel, MD, MPH
Commissioner
Massachusetts Department of Public Health
Division of Health Care Facility Licensure and Certification
99 Chauncy Street
Boston, MA 02111

Dear Dr. Bharel:

The purpose of this letter is to refer to the Massachusetts Department of Public Health (DPH), for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at Marlborough Hospital, 157 Union Street, Marlborough, MA (DPH Facility ID # 2103). The firm registered with the FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b]¹ on December 26, 2013. FDA investigators conducted an inspection of this outsourcing facility on May 21, 2014. A Form FDA 483 was not issued. Following the inspection, the firm deregistered this facility on June 8, 2014.

FDA subsequently inspected the facility from September 8, 2014, to September 17, 2014. A redacted 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/ORR/ORRElectronicReadingRoom/UCM431094.pdf>

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Marlborough Hospital 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.

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

¹ See Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

patients at risk. For example, the firm failed to demonstrate through appropriate studies that their ISO 5 is able to provide adequate protection of the area in which products intended or expected to be sterile are processed. Smoke studies under dynamic conditions were not performed to evaluate unidirectional airflow patterns over products in the ISO 5.

In its response to the Form FDA 483, received by FDA on October 6, 2014, Marlborough Hospital committed to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctible.

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 DPH 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 Rory Geyer, Compliance Officer, at (781) 587-7521, or by email at rory.geyer@fda.hhs.gov.

Sincerely,

Joseph S.
Matrisciano Jr -S



Digitally signed by Joseph S. Matrisciano Jr -S
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Joseph Matrisciano Jr.
Acting District Director
U.S. Food and Drug Administration
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