



U.S. Food and Drug Administration
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August 8, 2017

Mary T. Bassett, MD, MPH
Commissioner
New York City Department of Health and Mental Hygiene
42-09 28th Street
Long Island City, NY 11101-4132

Dear Dr. Bassett:

The purpose of this letter is to refer to the New York City Department of Health and Mental Hygiene (NYC DOHMH) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) observations regarding sterile practices made during an FDA inspection of a physician's office operated by William R. Grace, MD (New York State Department of Health (NYSDOH) License No. 108472), located at 945 5th Avenue, New York, NY 10021.

FDA inspected the facility from June 28, 2016, to July 8, 2016, in response to reports of an outbreak of *Exophiala dermatitidis* bloodstream infections in patients who had received intravenous medication prepared and administered in Dr. Grace's office. FDA investigators were accompanied for one day by a NYSDOH investigator and two days by a NYC DOHMH investigator. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm515113.pdf>.

During the inspection our investigators were only able to observe simulated sterile practices, as the office was operating under a NYC DOHMH Commissioner's Order dated May 31, 2016, and amended on June 30, 2016, which prohibited medication preparation and administration. Examples of observations made during the simulation that, in the inspectors' judgment, may have constituted violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) included: inadequate cleaning, disinfecting, and upkeep of the equipment used to produce and prepare sterile drug products; inadequate aseptic techniques demonstrated by the operators who prepare and handle sterile drug products; inadequate facility design to prevent microbiological contamination of sterile drug products; and drug products purporting to be sterile are not tested to determine conformance to such requirements.

In his response to the Form FDA 483, Dr. Grace committed to "meet recognized State requirements and other standards applicable to [a] physician office..." Following your September 27, 2016, re-inspection of the facility, your office notified Dr. Grace in a letter dated October 5, 2016, that the office met the minimum State and/or local standards required to re-open his practice and that the NYC DOHMH Commissioner's Order was rescinded, contingent upon several provisions. These provisions are related

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to medication preparation, storage and administration; implementation of infection control policies and procedures; retention of consultants for ongoing observation of clinical activities in the office; etc. In this letter, you also informed Dr. Grace of your plan to conduct periodic unannounced visits to assess compliance with the provisions of the letter.

After review of the record and with due consideration given to your office's expedient handling of the matter, FDA does not intend to take further action with regard to the findings of our inspection at the present time. We believe that the corrective actions have been, and will continue to be, appropriately overseen by the NYC DOHMH. Please notify us if you become aware of any adverse events or quality concerns associated with products made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

If you have additional questions, please contact Frank Verni, Compliance Officer, at (718) 662-5702, or by email at Frank.Verni@fda.hhs.gov.

Sincerely,

Diana

Amador-toro

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Digitally signed by Diana Amador-toro -S
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Diana Amador-Toro,
Division Director/OPQ Division 1
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