



Philadelphia District Office
US Customs House, Room 900
200 Chestnut Street
Philadelphia, PA 19106

Tel: 215-597-4390

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 28, 2017

David Dryden
Executive Secretary
Delaware State Board of Pharmacy
861 Silver Lake Boulevard
Cannon Building, Suite 203
Dover, Delaware 19904

RE: FDA Inspection of Nemours Alfred I. duPont Hospital for Children

Dear Mr. Dryden:

The Food and Drug Administration (FDA) is referring to the Delaware State Board of Pharmacy (BOP) for appropriate follow-up, our concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Delaware BOP, Nemours Alfred I. duPont Hospital for Children, 1600 Rockland Rd, Wilmington, DE 19803-3607 (hospital pharmacy, License #A6-0000366).

FDA inspected the firm from June 21, 2016 to June 29, 2016, accompanied by a Delaware state investigator. A redacted copy of a Form FDA 483 that documents our investigators'

observations from the inspection can be found at

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationandPolicy/ORA/ORAElectronicReadingRoom/UCM514655.pdf>.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Nemours Alfred I. duPont Hospital for Children 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.

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 patients at risk. Examples of deviations observed during our inspection include:

1. The firm does not use a sporicidal agent or sterile wipes to clean the ISO 5 area.
2. Technicians were observed introducing nonsterile components into the ISO 5 hood without disinfection.
3. Technicians were observed frequently exiting the ISO 7 Clean Room to the ISO 8 Ante Room, while using non-sterile wipes as a barrier between the gloved hand and door handle to regain access to the ISO 7 Clean Room to continue aseptic processing. In addition, sterile gloves were not changed during the process.
4. The door between the ISO 8 and ISO 7 area is constructed of wood and is not an easily cleanable surface.
5. Technicians were observed leaning their upper torso into the ISO 5 area while cleaning. Gowns, facemasks and hair nets worn are not sterile, and the method of gowning does not cover the face and neck allowing exposed facial skin and hair.
6. There is no evidence that smoke studies are conducted under dynamic conditions. No description was provided of the conditions created by the vendor that would represent actual processing conditions. It was also stated that technicians are not present to conduct simulated processing at the time smoke studies are performed by the vendor.

Nemours Alfred I. duPont Hospital for Children committed to FDA, in their written responses dated July 21, 2016, July 22, 2016 and October 19, 2016, to correct the deviations documented in the Form FDA 483 and provided evidence in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review, 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, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Delaware State BOP for appropriate follow-up. 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 Yvette Johnson, Compliance Officer, at (215) 717-3077, or by email at Yvette.Johnson@fda.hhs.gov.

Sincerely,



Anne Johnson
District Director
Philadelphia District Office