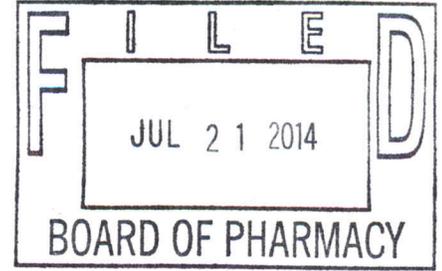


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STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF THE	:	Administrative Action
PERMIT OF	:	
	:	
Pharmacy Creations, LLC	:	SECOND INTERIM CONSENT ORDER
PERMIT #28RS00593300	:	
	:	
TO OPERATE AS A PHARMACY	:	
IN THE STATE OF NEW JERSEY	:	

This matter was opened to the New Jersey State Board of Pharmacy (the "Board") upon the receipt of information on or about June 27, 2014 indicating that 50 ml vials of Ascorbic Acid injectable 500mg/ml compounded and dispensed by Pharmacy Creations, LLC, located at 540 Route 10 West, Randolph, New Jersey may have been contaminated with mold.

Previously, on May 14, 2014, Pharmacy Creations, LLC entered an Interim Consent Order with the New Jersey Board of

Pharmacy which required the evaluation and ongoing monitoring of sterile compounding and related activities at Pharmacy Creations, LLC.

Following the notification of preliminary positive result for mold growth from Front Range Laboratories, on or about June 27, 2014 Pharmacy Creations, LLC initiated an immediate patient-level recall of the tested Lot in coordination with the FDA and the Board. To date, Pharmacy Creations has not received any reports that any patient who received a prescription from the Lot in question was adversely affected. In addition to the recall, Pharmacy Creations, LLC reports that it took the following actions in an attempt to systematically establish the cause of the sample's contamination and to assure sterility of all sterile preparations:

* In cooperation with the Board, Pharmacy Creations voluntarily discontinued shipping orders for any sterile preparations pending the results of sterility testing.¹

* Pharmacy Creations requested that Front Range Laboratories retest the sample and sent samples from the suspect Lot to two other independent laboratories for further analysis.

¹ Subsequent to receipt of 14-day negative lab results from Front Range and two other independent laboratories, prior to the entry of this Order and with the approval of the Board, Pharmacy Creations began shipping patient specific prescriptions on or about July 17, 2014 for post-operative ophthalmic medications for those patients who were previously scheduled for surgery.

14-day testing results from all three labs showed negative for microbial growth, including negative for mold growth.²

* Pharmacy Creations reviewed all worksheets for sterile preparations compounded in the days surrounding the preparation of Ascorbic Acid 06062014@8 for sterility results. The review indicated that 100% of the sterile products compounded for multiple days before and after the preparation of the Lot showed negative results for microbial growth as documented by sterile in-house testing and testing at contracted independent laboratories.

* Pharmacy Creations, LLC thoroughly cleaned all compounding aseptic isolators (CAIs) and compounding areas. Surface sampling was conducted within each CAI on 2 types of media - TSA & SDA (appropriate mediums for both bacterial and mold growth). No growth was detected at any location. In addition, surface sampling is routinely conducted as part of ongoing environmental monitoring.

* Pharmacy Creations, LLC engaged an independent certification company to recertify the aseptic compounding areas. All sterile compounding staff have initiated or completed media fill simulations, fingertip testing, aseptic processing, garbing, cleaning and hand hygiene evaluations. All

² Samples were also sent to the FDA and CDC. Results are not yet available, however, given the breadth of other information currently available, the Board is reasonably assured that this consent order is sufficiently protective of the public's health, safety and welfare.

testing and procedure evaluations were compliant with USP <797> guidelines and showed no evidence of microbial growth.

* Pharmacy Creations revised their policy and procedures to reflect new practices of quarantining all sterile preparations until receipt of 14-day sterility results from contracted laboratories. Any orders or prescriptions that cannot be quarantined, due to limited stability or emergency need, will not be filled by Pharmacy Creations.

* Pharmacy Creations retained LDT Health Solutions to review the testing results from all three laboratories and environmental certification contractors. LDT Health Solutions opined that the data provided by Front Range is likely "false positive" for mold.

The parties, having agreed to entry of this Interim Order, without further formal proceedings, and Pharmacy Creations, LLC, having agreed and given voluntary consent to the within Order and waiving any right to a hearing, and the Board finding the within disposition adequately protective of the public health, safety and welfare, and other good cause having been shown;

IT IS, therefore, on this 21st day of July, 2014

ORDERED THAT:

1. All terms and conditions of the Interim Order filed on May 14, 2014 remain in full force and effect.

2. Pharmacy Creations, LLC. may resume all shipments of medications upon the filing of this Order.

3. The Pharmacist-in-Charge at Pharmacy Creations shall report all preliminary and confirmed incidents of product contamination to the Board within 48 hours of becoming aware of such incidents.

4. In the event of any future preliminary or confirmed incidents of product contamination, Pharmacy Creations, LLC shall immediately obtain two (2) independently performed 14-day sterility reports per lot number, following USP <71> procedures. Should either or both of the two independently performed 14-day sterility reports confirm contamination, Pharmacy Creations agrees to immediately cease and desist all sterile compounding until further Order of the Board and shall comply with all requirements outlined in the May 14, 2014 Order regarding application to resume sterile compounding. Consistent with the requirements outlined in the May 14, 2014 Order, Pharmacy Creations, LLC shall engage LDT Health Solutions to provide the Board of Pharmacy with a report and the Board will arrange for an inspection of the pharmacy as soon as commercially reasonable to confirm any findings of LDT Health Solutions.

5. Pharmacy Creations shall quarantine all sterile preparations until receipt of 14-day sterility results - negative for contamination - from contracted laboratories. Any

orders or prescriptions that cannot be quarantined, due to limited stability or emergency need, will not be filled by Pharmacy Creations.

6. All costs associated with compliance with this Order shall be the responsibility of, and paid directly by, Pharmacy Creations, LLC.

7. This Consent Order shall not be construed to be a disciplinary action or sanction of any kind, nor as an admission of liability on the part of the pharmacy.

8. The entry of within Order is without prejudice to the further investigation and/or prosecution by the Board, the Attorney General, or any other regulatory or law enforcement agency of any violations by Pharmacy Creations, LLC of any statutes or regulations governing the practice of pharmacy in the State of New Jersey or any violations of law, including but not limited to any pending matters under investigation.

NEW JERSEY STATE BOARD OF PHARMACY

Thomas F.X. Bender, Jr.

By: _____

Thomas F.X. Bender, R.Ph.,
President

I have read the within Order and understand it. I agree to be bound by its terms and hereby consent to it being entered by the New Jersey Board of Pharmacy.

Randle House, Pharm. D.

Vice President of Pharmacy Operations
Authorized by and on behalf of Pharmacy Creations, LLC, a wholly owned subsidiary of Imprimis Pharmaceuticals, Inc
Consent as to form and entry:

Mark Boesen

PRINT NAME: Mark Boesen

Attorney for
Pharmacy Creations, LLC