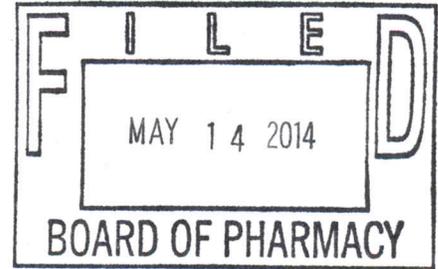


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JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law, 5th Floor
124 Halsey Street
P.O. Box 45029
Newark, New Jersey 07101



By: Megan Cordoma
Deputy Attorney General
(973) 648-4735

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 :
 : **INTERIM CONSENT ORDER**
 :
 Pharmacy Creations, LLC :
 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 an inspection report of Pharmacy Creations, LLC, located at 540 Route 10 West, Randolph, New Jersey.¹ The report was dated June 17, 2013, and documents a myriad of concerns related to the Board's regulations regarding sterile compounding as well as the

¹ Ownership of Pharmacy Creations, LLC became a wholly owned subsidiary of Imprimis Pharmaceuticals, Inc. on or about April 1, 2014.

requirements set forth in Chapter <797> of the United States Pharmacopeial Convention ("USP"). These concerns include, in the area of sterile compounding, environmental monitoring and documentation, cleaning and disinfecting, training and garbing, and quality of active pharmaceutical ingredients ("API"). Additionally, staff at the pharmacy attempted to bar inspector's access during the inspection. A copy of this report has been provided to the Pharmacy. In a response provided to the Board office on or about April 24, 2014, Pharmacy Creations, LLC outlined a plan of action to address the concerns highlighted during the June 2013 inspection which includes important and desirable actions, many of which Pharmacy Creations, LLC has already implemented. Despite the inspection concerns noted in the June 2013 report, after the issuance of the June 2013 report inspectors from the Food & Drug Administration and the Pharmacy Compounding Accreditation Board inspected the pharmacy and found the facility to be in substantial compliance with USP <797> standards. In addition, the State of Indiana Board of Pharmacy concluded as a finding of fact that Pharmacy Creations, LLC was compliant with USP <797> standards in an order issued on October 17, 2013.

Out of an abundance of caution, and in order to protect the public, the Board has determined that confirmation that the pharmacy is in compliance with New Jersey Statute and Regulation and USP <797> by way of an evaluation and written report

from a Board approved monitor knowledgeable in high risk sterile compounding is warranted.

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 14th day of May, 2014

ORDERED THAT:

1. Pharmacy Creations, LLC shall immediately contract with a third-party monitor (the "Monitor") pre-approved by the Board to review all compounding operations of the pharmacy. The Monitor shall ensure that the Pharmacy addressed the various issues of concern documented in the inspection report, and is in compliance with the requirements of USP and the regulations of the Board.

2. Pharmacy Creations, LLC agrees that the Monitor shall engage in a candid conversation with the Board President regarding his evaluation of the Pharmacy no later than 5:00PM EDT on Friday May 16, 2014. If this conversation does not take place in a timely manner, or the oral report of the Monitor indicates any current serious risk related to sterile compounding

which in the Board's sole discretion places the public's health safety and welfare at risk, Pharmacy Creations, LLC agrees to immediately cease and desist all sterile compounding until further Order of the Board with an exception for the limited purpose of allowing monitored observation of operations and compounding procedures by a monitor as set forth below. Compounded sterile preparations made for the purpose of observation under the supervision of the Monitor shall not be released to the public for use or consumption.

3. Pharmacy Creations, LLC shall ensure that the Monitor submits a comprehensive written report (as described in paragraph 4, below) to the Board on or before May 23, 2014. If the report is not received on or before May 23, 2014, or as soon as is commercially practicable, or if the report indicates any current serious risk related to sterile compounding which in the Board's sole discretion places the public's health safety and welfare at risk, Pharmacy Creations, LLC agrees to immediately cease and desist all sterile compounding until further Order of the Board with an exception for the limited purpose of allowing monitored observation of operations and compounding procedures by a monitor as set forth below. Compounded sterile preparations made for the purpose of observation under the supervision of the Monitor shall not be released to the public for use or consumption.

4. Pharmacy Creations, LLC shall provide proof of environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi on or before May 23, 2014. If the testing indicates any current serious risk related to sterile compounding which in the Board's sole discretion places the public's health safety and welfare at risk, Pharmacy Creations, LLC agrees to immediately cease and desist all sterile compounding until further Order of the Board with an exception for the limited purpose of allowing monitored observation of operations and compounding procedures by a monitor as set forth below. Compounded sterile preparations made for the purpose of observation under the supervision of the Monitor shall not be released to the public for use or consumption.

5. In the event that Pharmacy Creations LLC must cease and desist sterile compounding pursuant to the terms of this Order, prior to any application to resume sterile compounding operations, Pharmacy Creations, LLC shall furnish the Board with a report from the Monitor, which demonstrates review of all processes and procedures, and attests to compliance with all Board regulations and USP standards. Upon receipt of a request of Pharmacy Creations, LLC to resume sterile compounding operations, the Board will schedule a re-inspection of the pharmacy within 30 days to ensure that all concerns noted in prior inspection reports have been addressed. If requested

by the Board, the RPIC shall appear before the Board or a committee thereof, and testify regarding the pharmacy's adherence to all applicable laws, regulations and USP standards.

6. Subsequent to the initial review and evaluation described in paragraph three (3) above, Pharmacy Creations, LLC shall contract with a Monitor pre-approved by the Board to review all compounding operations of the pharmacy on at least four occasions before August 1, 2015 to ensure the pharmacy continues to be in compliance with the requirements of USP and the regulations of the Board. The Monitor shall evaluate Pharmacy Creations, LLC at unannounced visits and provide comprehensive reports to the Board at approximately three month intervals.

7. All costs associated with the monitoring outlined in this Order shall be the responsibility of, and paid directly by, Pharmacy Creations, LLC.

8. 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.

9. 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 including the June 17, 2013 Inspection referenced above.

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.
Dated:

Scott Karolchuck

Scott Karolchuck, R.Ph.,
on behalf of and duly authorized
by Pharmacy Creations, LLC
A wholly owned subsidiary of
Imprimis Pharmaceuticals, Inc.

Consent as to form and entry:

Otto W. Immel

Otto W. Immel, Quarles & Brady LLP
Attorney for Pharmacy Creations, LLC
A wholly owned subsidiary of
Imprimis Pharmaceuticals, Inc.