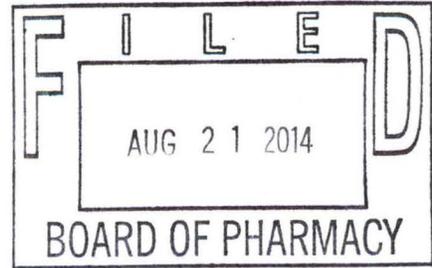


JOHN J. HOFFMAN
ACTING ATTORNEY GENERAL OF NEW JERSEY
Division of Law, 5th Floor
124 Halsey Street
P.O. Box 45029
Newark, New Jersey 07101

By: Megan Cordoma
Deputy Attorney General
(973) 648-4730



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
Specialty Rx, Inc. Pharmacy	:	
PERMIT #28RS00629700	:	
	:	
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 Specialty Rx, Inc. ("Specialty Rx"), located at 209 East 11th Street, Roselle, New Jersey. The report was dated August 23, 2013, and documents a myriad of concerns related to the Board's regulations regarding sterile compounding as well as the 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, compounding procedures, and quality of active pharmaceutical ingredients ("APIs").¹ In a response provided to the Board office on or about April 24, 2014, Specialty Rx outlined a plan of action to address the concerns highlighted during the August 2013 inspection and expressed its intention to evaluate and reconstruct its clean room. This response was found to be unsatisfactory by the Board.

Due to the potential danger to the public presented by improper practices associated with compounded sterile products, 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 Specialty Rx 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 August, 2014

ORDERED THAT:

¹ Additionally, Specialty Rx submitted a Pharmacy Permit Application for remodeling dated May 9, 2013 for work completed in December 2011 without Board authorization. Specialty Rx has explained that the current RPIC submitted the application immediately upon assuming employment as RPIC and upon the realization that the application was not previously submitted.

1. Specialty Rx 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 addresses the various issues of concern documented in the inspection report, and brings the pharmacy in compliance with the requirements of USP and the regulations of the Board.

2. Specialty Rx shall ensure that the Monitor submits a comprehensive written report (as described in paragraph 3, below) to the Board on or before September 2, 2014. If the report is not received on or before September 2, 2014, 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, Specialty Rx 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. Specialty Rx shall provide proof of environmental testing, pressure differential monitoring, and air and surface sampling for bacteria and fungi on or before September 2, 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, Specialty Rx 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. Subsequent to the initial review and evaluation described in paragraph three (3) above, Specialty Rx shall contract with a Monitor pre-approved by the Board to review all compounding operations of the pharmacy on at least four additional occasions before October 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 Specialty Rx at unannounced visits and provide comprehensive reports to the Board at approximately three month intervals.

5. If any report from 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, Specialty Rx 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.

6. In the event that Specialty Rx must cease and desist sterile compounding pursuant to the terms of this Order, prior to any application to resume sterile compounding operations, Specialty Rx 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 Specialty Rx to resume sterile compounding operations, the Board will schedule a re-inspection of the pharmacy to ensure that all concerns noted in prior inspection or monitoring 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.

7. Specialty Rx shall submit a remodeling application for and complete the proposed improvements to its compounding area to comply with USP General Chapter <797> and/or <800> on or before November 1, 2014. Specialty Rx shall advise the board in writing within 48 hours of the completion of the renovations.

8. All costs associated with the monitoring and renovations outlined in this Order shall be the responsibility of, and paid directly by, Specialty Rx

9. 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.

10. 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 Specialty Rx 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 August 2013 Inspection referenced above.

NEW JERSEY STATE BOARD OF PHARMACY

By:

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

Joseph J. Kubulak
Joseph J. Kubulak, on behalf of
and duly authorized by Specialty
Rx, Inc.

Consent as to form and entry:

Pamela Mandel 8/20/14
Pamela Mandel
Attorney for Specialty Rx, Inc.