BEFORE THE I	KANSAS BOARD OF PHARMACY	riied By
In the Matter of	hma som ay sidt at heegen state handl)	JUN 7 2021
RXQ COMPOUNDING, LLC) Case No. 20-230	KANSAS STATE BOARD OF PHARMACY
Pagintration No. 20 102520)	

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Pharmacy Board ("Board") and RXQ Compounding, LLC located in Albany, Ohio ("Respondent") as follows:

- 1. The Board is represented herein by its attorney, Randall J. Forbes of Frieden & Forbes, LLP, 1414 SW Ashworth Place, Suite 201, Topeka, Kansas 66604. The Respondent is represented herein by its attorney, _______.
- 2. The Board is the Kansas agency vested with the authority to carry out and enforce the provisions of the Kansas Pharmacy Law, K.S.A. 65-1626 *et seq.*, ("Act") including conducting hearings and proceedings to revoke, suspend or otherwise discipline a Kansas registration to operate as a wholesale distributor.
- 3. The Board has previously issued Respondent a registration as a wholesale distributor (Registration No. 5-103530). On June 30, 2020, the Board received Respondent's application to change its registration to an Outsourcing Facility ("Outsourcing Application"). Respondent's Outsourcing Application was granted.
- 4. K.S.A 65-1657(c) provides that it is unlawful for any entity to distribute at wholesale any drugs in Kansas without a registration issued by the Board.

5. Respondent hereby waives any further proof in this or any other proceeding before

or initiated by the Board with respect to this matter, and upon motion duly made, seconded, and

passed, the Board finds that

A. On June 30, 2020, the Board received Respondent's "Outsourcing Application",

which had been signed by Respondent's Pharmacist-in-Charge on June 29, 2020. Respondent's

Outsourcing Application was granted.

B. The Respondent's Outsourcing Application stated that it had not had a license or

registration disciplined.

C. In fact, on April 22, 2020, the State of Vermont Office of Professional Regulation

Board of Pharmacy entered a Stipulation and Consent Order disciplining Respondent ("Vermont

Order"). A true and correct copy of the Vermont Order Respondent is marked Exhibit A,

attached hereto, and incorporated herein by reference.

6. Upon motion duly made, seconded, and passed, the Board finds and concludes that

the events described in paragraph 5 above constitute grounds for disciplinary action against the

Respondent's Kansas Registration provided for herein, pursuant to K.S.A. 65-1627(f)(1).

7. The Board finds, concludes, and orders that the following disposition is just and

appropriate under the circumstances:

A. ADMINISTRATIVE FINE. Within ten (10) days of the Board entering the

Consent Order provided for herein, Respondent shall pay to the Kansas Pharmacy Board an

administrative fine in the amount of One Thousand Dollars (\$1,000.00).

B. PROBATION. The Board hereby orders that Respondent's Kansas registration as

an Outsourcing Facility shall be paced on a probationary status for a period of three (3) years

from the effective date of the Consent Order contemplated hereby ("Probationary Period").

During the Probationary Period, the Respondent shall:

- i. Fully comply with all of the requirements set forth in the Vermont Order.
- ii. Provide the Board with un-redacted copies of any Federal Drug Administration ("FDA") Form 483 observations and/or Warning Letters within ten (10) day of receipt. Respondent shall further provide the Board with any response to such FDA actions within ten (10) days of sending the response to the FDA.
- iii. Provide the Board with un-redacted copies of any inspection report prepared by or on behalf of the Ohio Board of Pharmacy within ten (10) days of receipt.
- iv. Provide the Board with un-redacted copies of any action taken by a federal or state regulatory agency within ten (10) days of receipt. This reporting requirement shall apply to any and all actions taken by a federal of state regulatory agency regardless of whether it is considered to be a disciplinary action.
- v. Provide the Board notice within ten (10) days of any recall pursuant to the procedures required by K.A.R. 68-14-7b(g)(2).
- vi. Provide the Board notice within ten (10) days of any seizure of any product shipped into the State of Kansas.
- vii. Provide to the Board within ten (10) days of the beginning of each quarter a report detailing Respondent's quality assurance program regarding out of compliance issues and Respondent's proposed solution(s).

- viii. Provide the Board notice within five (5) days of any change in Respondent's Pharmacist-in-Charge
- C. OTHER REQUIREMENTS. Respondent acknowledges and agrees that as a condition of this Stipulation and Consent Order it must, and the Board further orders the Respondent to:
 - i. Comply fully with this Stipulation and Consent Order;
 - ii. Comply fully with the Kansas Pharmacy Act, the Board's rules and regulations and all state and federal laws relating to Kansas pharmacies;
- Respondent agrees that all information in the possession of the Board's Investigation Member, its staff, its investigators and or its attorney regarding the investigation which lead to this disciplinary action and all information discovered during the pendency of the disciplinary action may be disclosed to and considered by the Board as part of the presentation and consideration of the proposal of settlement in the form of this Stipulation and Consent Order and the Final Order provided for herein, with or without the presence of the Respondent or its attorney. In the event that this Stipulation and Consent Order and the Final Order provided for herein are not accepted and approved by the Board, the Respondent further waives any objection to the Board members' consideration of this Stipulation and Consent Order or the information mentioned in the preceding sentence and further agrees to waive any claim of due process violation or the right to seek the disqualification of any Board member as a result of the Board member's consideration of said document and information.
- 9. The stipulations contained herein shall not become binding until this Stipulation and Consent Order is approved by the Board and the Consent Order provided for herein is entered by the Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either the Board of the Respondent. The Respondent acknowledges that the

approval of the Board's Investigation Member or its attorney shall not constitute the approval of the Board or bind the Board to approve this Stipulation and Consent Order.

- 10. The Respondent agrees that this Stipulation and Consent Order is in conformance with Kansas and federal law and the Board has jurisdiction to enter into it and enter the Final Order provided for herein. The Respondent further agrees, for purposes of this matter, that the Kansas Pharmacy Act, K.S.A. 65-1626 *et seq.* is constitutional on its face and as applied in this case.
- 11. This Stipulation constitutes the entire agreement of the parties and may only be modified by a subsequent writing signed by them. The agreement shall be interpreted in accordance with the laws of the State of Kansas.
 - 12. The Respondent acknowledges that it has the following rights:
 - (a) To have formal notice of charges served upon it;
 - (b) To file a response to the charges;
- (c) To have notice of and participate in a formal adjudicative hearing with the Board or its designee making specific findings of facts and conclusions of law based only upon evidence admitted at such hearing; and
- (d) To take advantage of all applicable provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501 et seq. and the Kansas Judicial Review Act, K.S.A. 77-601 et seq.

The Respondent freely waives these rights and acknowledges that said waiver is made voluntarily and in consideration of the Board's limiting the disciplinary action taken against it to those provided for herein. The Respondent further waives the right to seek reconsideration or appeal or otherwise contest this Stipulation and Consent Order provided for herein.

13. The Respondent acknowledges that it enters into this Stipulation and Consent

Order freely and voluntarily after consultation with counsel of its choosing. The Respondent

further acknowledges that it has read this Stipulation and Consent Agency order in its entirety,

that it understands its legal consequences and that it agrees that none of its terms are

unconscionable, arbitrary, or capricious.

14. Time is of the essence to this Stipulation and Consent Order. Respondent

acknowledges and agrees that any violation of this Stipulation and Consent Order shall constitute

a willful violation of a lawful Board order and grounds for further disciplinary action against it.

The pendency of any disciplinary action arising out of an alleged violation of this Stipulation and

Consent Order shall not affect the obligation of Respondent to comply with all terms and

conditions of this Stipulation and Consent Order.

15. This Stipulation and Consent Order constitutes the entire and final agreement of

the parties. In the event any provision of this Stipulation and Consent Order is deemed invalid

or unenforceable by a court of competent jurisdiction, it shall be severed and the remaining

provisions of this Stipulation and Consent Order shall be given full force and effect.

16. Upon approval and entry of the Final Order by the Board, this Stipulation and

Consent Order shall be a public record in the custody of the Board.

17. This Stipulation and Consent Order shall become effective on the day it is

approved, accepted, and made an order of the Board by way of signature of the Board's

authorized representative.

18. The Respondent acknowledges that it has been advised by the Board that it would

have the right within 15 days after service of the Final Order provided for herein to file a petition

for reconsideration with the Board and the right within 30 days after service of the Final Order

provided for herein to file a petition for judicial review in the District Court of Shawnee County, Kansas in accordance with the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.* and to serve such a petition for judicial review on the Kansas Board of Pharmacy by serving Alexandra Blasi, JD, MBA, its Executive Secretary at 800 SW Jackson St., Suite 1414, Topeka, KS 66612. The Respondent hereby waives those rights.

ENTERED AND EFFECTIVE this ______, day of ________, 2021.

KANSAS BOARD OF PHARMACY

By:

R. JØNATHANBRUNSWIG, President

AGREED AND APPROVED BY:	
RXQ Compounding, LLC 2364 Blizzard Lane Albany, OH 45710 By:	3/19/2/ Date
Dr. Terica Gatewood Investigation Member	<u>6/2/2/</u> Date
Attorney for RXQ Compounding, LLC	Date
Randall J. Forbes, KS#09089 MO#64335 FRIEDEN & FORBES, LLP 1414 SW Ashworth Place, Suite 201	04/12/2021 Date

Topeka, KS 66604 (785) 354-1100

Attorney for Kansas Pharmacy Board

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing STIPULATION AND CONSENT ORDER was served by depositing same in the United States mail, postage prepaid, this The day of June, 2021 addressed to:

Randall J. Forbes FRIEDEN & FORBES, LLP 1414 SW Ashworth Place, Suite 201 Topeka, KS 66604

RXQ Compounding, LLC c/o Edward M. Zatta, Manager 1802 Hamilton Place Steubenville, OH 43952

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