

BEFORE THE KANSAS BOARD OF PHARMACY

Filed By

JUN 7 2021

KANSAS STATE BOARD OF PHARMACY

In the Matter of)
)
MED-PHARMEX, INC.)
)
)
)
Registration No. 5-30994)

Case No. 20-228

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Pharmacy Board (“Board”) and Med-Pharmex, Inc. located in Pomona, California (“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, David J. Horowitz, Hogan Lovells US LLP, Columbia Square, 555 Thirteenth Street, NW, Washington, DC 20004.

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. Respondent made application to the Board to renew its registration as a wholesale distributor.

4. Respondent has distributed at wholesale drugs into Kansas.

5. Respondent, without admitting or denying the facts represented herein, 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. Since May 28, 2015 Respondent has continuously held Kansas Wholesale Distributor Registration Number 5-30994 (“Kansas Registration”) and has distributed at wholesale drugs into Kansas. On June 30, 2020, the Board received Respondent’s renewal application to be registered by the Board as a Wholesale Distributor (“Application”). The Application was granted.

B. The Board has determined that on or about May 17, 2019, the United States Food and Drug Administration (“FDA”) issued a Form 483 Inspection Report for an inspection performed by the FDA from May 1, 2019 through May 17, 2019 at the Respondent’s California facility (“Form 483”). A true and correct copy of the Form 483 is marked Exhibit A, attached hereto, and incorporated herein by reference.

C. The Observations made in the Form 483 are evidence that while Respondent its Kansas Registration and distributed drugs into Kansas it operated in violation of K.A.R. 68-147(a), K.A.R. 68-14-7(e)(1) and provisions of the Federal Food Drug and Cosmetic Act.

6. Upon motion duly made, seconded and passed, the Board finds and concludes that the events described in paragraph 5 above constitute the operation of a wholesale distributor in a manner that violates the Act and the Regulations of the Board and is therefore grounds for disciplinary action against the Respondent’s Kansas Registration provided for herein, pursuant to K.S.A. 65-1627(f)(6) for violations of K.A.R.68-14-7(a), K.A.R. 68-14-7(e)(1), and K.A.R. 6814-7(i).

7. The Board finds, concludes, and orders that the following disposition is just and appropriate under the circumstances:

A. ADMINISTRATIVE FINE. Respondent shall pay to the Board an administrative fine in the amount of Five Thousand Dollars (\$5,000.00). One Thousand Dollars of the fine shall be paid by Respondent to the Board within ten (10) days of the Board entering the Consent Order

provided for herein. Payment of the remaining Four Thousand Dollars (\$4,000.00) of the fine shall be suspended during the Probation Period provided for herein. If the Board shall determine in its discretion that Respondent, at any time during the Probation Period, has violated the terms of this Stipulation and Consent Order, violated any applicable statutes or regulations, or committed any act that would be a basis for discipline pursuant to the Act, the Four Thousand Dollar (\$4,000.00) balance of the fine shall become immediately due and payable to the Board in addition to any other discipline the Board determines to be appropriate. If the Board shall not determine in its discretion that Respondent, at any time during the Probation Period, has violated the terms of this Stipulation and Consent Order, violated any applicable statutes or regulations, or committed any act that would be a basis for discipline pursuant to the Act, the Four Thousand Dollar (\$4,000.00) balance of the fine shall not become payable to the Board and shall at the end of the Probation Period be waived.

B. PROBATION. Respondent's Kansas Registration shall be placed on probationary status for a period of 3 years from the effective date of the Consent Order provided for herein ("Probation Period").

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;

8. 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 or 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;

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(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 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 7th day of June, 2021.

KANSAS BOARD OF PHARMACY

By: 
DR. JONATHAN BRUNSWIG, President

AGREED AND APPROVED BY:

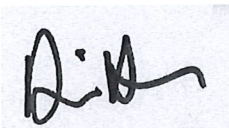
Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767

By: 
Paul R. Hays
President & CEO


12/18/2020
Date


Dr. Terica Greenwood
Investigation Member

6/3/21
Date


David J. Horowitz
HOGAN LOVELLS US LLP
Columbia Square
555 Thirteenth St., NW
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(202) 637-5600
Attorney for Med-Pharmex, Inc.

12/18/2020
Date


Randall J. Forbes, KS#09089 MO#64335
FRIEDEN & FORBES, LLP
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(785) 354-1100
Attorney for Kansas Pharmacy Board

05/20/2021
Date

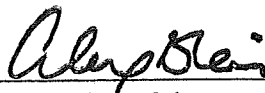
CERTIFICATE OF SERVICE

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 1st day of June, 2021 addressed to:

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

Med-Pharmex, Inc.
c/o Gerald Macedo
2727 Thompson Creek Road
Pomona, CA 91767

David J. Horowitz
HOGAN LOVELLS US LLP
Columbia Square
555 Thirteenth St., NW
Washington, DC 20004



Representative of the
KANSAS BOARD OF PHARMACY