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Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

December 6, 2022

Partell Specialty Pharmacy
5835 South Eastern Ave Ste 101
Las Vegas, NV 89119

RE: Case No. 22-051

Dear To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of)
)
Partell Specialty Pharmacy)
)
Registration No. 22-116612)

Case No. 22-051

SUMMARY ORDER

NOW on this 6th day of December, 2022, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Director, the matter of Partell Specialty Pharmacy (“Respondent”).

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board’s Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. On November 23, 2021, the Board received Applicant’s Application for Nonresident Pharmacy. Applicant previously applied February 2019, which would have been denied based upon Applicant’s failure to report discipline from the Texas Board of Pharmacy and an FDA 483 from early 2018. However, Applicant chose to withdraw the previous application in lieu of disciplinary action.

2. In 2018, Applicant provided list of observations from the FDA sterile compounding inspection. There were 10 observations on the list. The result of the inspection was the immediate and permanent ceasing of all sterile compounding by the pharmacy and recall of all their products.

The observations include but are not limited to: Using inadequate and non-pharmaceutical grade filters to sterilize products; Cycle parameters for heat sterilization not verified to be lethal; Final containers/closures for sterile products not sterilized or depyrogenated; Disinfecting agents, wipes, and pads for cleaning ISO 5 areas not sterile; Sporocidal agents not being applied for full dwell time; Inadequate cleaning of utensils used with hazardous drugs to prevent cross-contamination of non-hazardous drugs; Non-sterilized and non-depyrogenated tools used in sterile compounding; Inadequate Environmental Monitoring; Not investigating root cause of Aspergillus found in ISO 5 area.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1657(f), the Board may limit, condition, revoke, suspend or place in a probationary status a registration or deny an application for issuance or renewal of any registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

2. Pursuant to K.S.A. 65-1627(e)(1), the Board may deny an application or renewal, limit, condition, revoke, suspend or place in a probationary status the registration of any pharmacy upon a finding that such pharmacy has been operated in such manner that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

3. Pursuant to K.S.A. 65-1627(e)(4), the Board may deny an application or renewal, limit, condition, revoke, suspend or place in a probationary status the registration of any pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country, a

certified copy of the record of the action of the other jurisdiction being conclusive evidence thereof. When the board determines that action under this subsection requires the immediate protection of the public interest, the board shall conduct an emergency proceeding in accordance with K.S.A. 77-536, and amendments thereto, under the Kansas administrative procedure act.

4. Pursuant to K.S.A. 65-1657(d), each nonresident pharmacy shall comply with all the statutory and regulatory requirements of Kansas regarding drug product selection laws whether or not such compliance would be in conflict with specific laws or rules and regulations of the state in which the pharmacy is located, except that compliance that constitutes only a minor conflict with specific laws or rules and regulations of the state in which the pharmacy is located would not be required under this subsection.

5. Pursuant to K.S.A. 65-1657(a) applications for a nonresident pharmacy registration shall be made on a form prescribed and furnished by the Board.

6. Pursuant to K.A.R. 68-7-12a, each nonresident pharmacy must provide proof of a satisfactory inspection conducted within the previous 18-month period by the licensing entity of the state where the pharmacy is located or a third party recognized by the Board.

7. The Board requires Applicant provide the most recent inspection report conducted within the previous 18-month period by the state of residence or the National Association of Boards of Pharmacy, detailed ownership information, information concerning any disciplinary history for the facility, proof of valid registration in the state of residence, information concerning any permits held in other states, etc.

8. Applicant's history of Texas discipline, as well as Applicant's multiple FDA sterile compounding violations represent a concern for the protection of the public, indicate that Applicant has failed to comply with the requirements of the practice of pharmacy in the past, and

does not have a thorough, complete, and satisfactory inspection. These are bases for limiting and conditioning a non-resident pharmacy registration pursuant to K.S.A. 65-1627 and 65-1657.

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby GRANTED subject to the following limitation and condition: Applicant shall provide the Board with a satisfactory sterile compounding inspection prior to dispensing any compounded sterile products into Kansas.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.
2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.
3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.
4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

12/6/2022
Date

Ally Klein
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 6th day of December, 2022 deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Partell Specialty Pharmacy
5835 South Eastern Ave Ste 101
Las Vegas, NV 89119



Kansas Board of Pharmacy Staff