BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 20-223
Tailor Made Compounding, LLC	)	
	)	
Registration No. 22-108376	)	
	)	

SUMMARY ORDER OF DENIAL

NOW on this 2nd day of March, 2021, comes before the Kansas Board of Pharmacy ("Kansas Board"), through its authorized Investigation Member, the application of Tailor Made Compounding, LLC ("Applicant") for renewal of its registration as a nonresident pharmacy.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq* ("Pharmacy Act")., and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Investigation Member enters this Summary Order of Denial in the above-captioned matter. After reviewing the application materials, the Board's records, other relevant materials, and being otherwise duly advised in the premises, the Investigation Member makes the following findings, conclusions, and order:

FINDINGS OF FACT

For purposes of this Order, the Board's Investigative Member makes the following findings of fact:

1. The Kansas Board has previously issued Applicant nonresident pharmacy registration number 22-108379.

2. On June 3, 2020, the Kansas Board received Applicant's application for renewal of its registration as a nonresident pharmacy ("Applicant's Application").

3. K.A.R. 68-7-12a(a)(3) provides that a nonresident pharmacy registered with the Board must at all time maintain a record of a satisfactory inspection conducted within the previous 18-month period by a licensing entity of the state where the pharmacy is located or if unavailable by a third party recognized by the Board to inspect.

4. On October 24, 2018, as a result of an inspection of Applicant's facility, the United States Food and Drug Administration ("FDA") issued a Form 483 containing 12 deficiency observations, those observations included:

a. Investigations of unexplained discrepancy did not extend to associated products;

b. Procedures to prevent microbiological contamination of sterile products were not established, written, and followed (media fills, hold times);

c. Smoke studies performed under static conditions and do not include lyophilization processes;

d. Nonsterile bactericidal agent was used to clean hood;

e. Aseptic processing areas deficient in monitoring environmental conditions;

f. Labels were not examined for conformity to master production records;

g. Potency testing was not performed with any set schedule or frequency;

h. Component identity testing was not performed;

i. No hold times for sterilized glassware were established and no studies to assure a 3-log reduction in endotoxins were performed; and

j. Routine calibration of equipment was not performed.

5. On October 21, 2019, a National Association of Boards of Pharmacy Verified Pharmacy Program inspection report was issued regarding inspection of Applicant's facility and identifying the following deficiencies:

a. Master formulation records were not updated for new equipment;

b. Several ceiling tiles in ISO buffer rooms were not sealed into place;

c. Temperature readings were outside of storage temperatures of 68F-77F; and

d. ACD's were not used in media fill challenges.

6. On April 1, 2020, the FDA issued a Warning Letter to Applicant after evaluation of the inspection and facility responses to the inspections of Applicant's facility on August 20, 2018 and October 24, 2018 noting the following items and violations:

a. The facility failed to meet the conditions of 503A by compounding with products that are not the subject of an applicable monograph, are not the component of an FDA-approved human drug, and do not appear on the 503A bulks list. The manufacture of these ineligible products is subject to FDA cGMP requirements. Investigators observed significant cGMP violations at the facility, including: failure to establish procedures to prevent microbiological contamination; failure to establish an adequate system for cleaning and disinfecting; failure to test to verify component identity; failure to routinely calibrate equipment; and failure to thoroughly investigate unexplained discrepancies;

b. Drug products intended to be sterile were prepared, packed, or held under insanitary conditions (no hold times for sterilized items, non-sterile

disinfectant in ISO 5, media fills not performed under most challenging conditions, smoke studies not performed under dynamic conditions);

c. The facility did not have any FDA-approved applications on file for the ineligible drug products they compounded;

d. Misbranded ineligible drug products existed due to inadequate labeling; and

e. The FDA was not able to fully evaluate the corrective actions for insanitary conditions in TMC's response due to insufficient information and documentation.

7. On October 29, 2020, Applicant entered into a "Plea Agreement" filed in Criminal Action No. 3:20-CR-15-GFVT pending before the United States District Court for the Eastern District of Kentucky, Central Division, whereby Applicant plead guilty to a misdemeanor violation of 21 U.S.C. § 331(d) for selling selective androgen receptor modulators classified under the federal Food, Drug, and Cosmetic Act as an unapproved new drug ("Plea Agreement"). The Plea Agreement resulted in a conviction for a violation of the federal Food, Drug and Cosmetic Act.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1627(e)(1), the Kansas Board may deny the renewal of a pharmacy registration if the pharmacy has been operated in a manner that violates the Pharmacy Act or the Kansas Board's regulations. Applicant's failure to comply with K.A.R. 68-7-12a(a)(3) is a violation of a Board regulation.

2. Pursuant to K.S.A. 65-1627(e)(2), the Kansas Board may deny the renewal of a pharmacy registration if the owner of a pharmacy, or in this instance the pharmacy, has been convicted of a violation of the federal Food, Drug, and Cosmetic Act.

3. The inspection results detailed in paragraph 6 and the conviction detailed in paragraph 7 are each a basis to deny Applicant's Application.

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby DENIED.

NOTICES

The Applicant is hereby notified as follows:

4. The Applicant 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.

5. If a hearing is not requested as described above, this Summary Order denying Applicant's Application for renewal of its registration as a nonresident pharmacy shall become a final order of the Kansas Board, effective upon the expiration of the time to request a hearing.

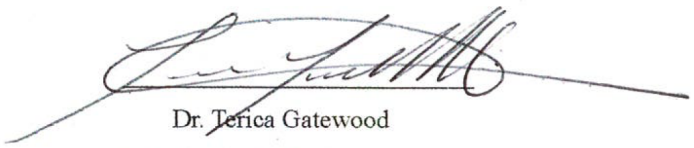
6. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

7. 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, JD, MBA
Executive Director
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

2/26/2021
Date



Dr. Terica Gatewood
Investigation Member
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 2nd day of March, 2021, deposit in the United States Mail, postage prepaid, a copy of the foregoing Summary Order of Denial, properly addressed to the following:

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

Tailor Made Compounding, LLC
c/o Paul Joseph Sharpe, Pharmacist-in-Charge
200 Moore Dr.
Nicholasville, KY 40356

Irving L. Wiesen
IRVING L. WIESEN, P.C.
420 Lexington Ave., Suite 200
New York, NY 10170

Representative of the
Kansas Board of Pharmacy