BEFORE THE KANSAS STATE BOARD OF PHARMACY

| In the Matter of |
|--------------------------|
| Merz North America, Inc. |
| Applicant |

Case No. 21-205

SUMMARY ORDER OF DENIAL

NOW, on this 12th day of October 2021, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Merz North America, Inc. ("Applicant").

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 provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order of Denial in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On December 17, 2020, the Board received Applicant's application for registration as a sample distributor in the State of Kansas ("Applicant's Application").

2. On March 10, 2021, the Board sent Applicant an email requesting several required information items that were missing from Applicant's Application, specifically Applicant's detailed ownership information, a list of other states where Applicant is registered, and list of the drug samples being distributed.

3. On May 7, 2021, the Board sent a final letter to Applicant's address of record requesting the above information and providing a response deadline of June 11, 2021.

4. To date, the Board has not received the required application documents or any further

800 SW Jackson St., Suite 1414 Topeka, KS 66612

Alexandra Blasi, Executive Secretary

October 12, 2021

Merz North America, Inc. 13900 W Grandview Parkway Sturtevant WI 53177

RE: Case No. 21-205

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 <u>Pharmacy.Compliance@ks.gov</u>.

Sincerely,

Kansas Board of Pharmacy

Enclosure



Phone: (785) 296-4056 Fax: (785) 296-8420 pharmacy@ks.gov www.pharmacy.ks.gov

Laura Kelly, Governor

correspondence from Applicant.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1645(a) application for registration or permits under K.S.A. 65-1643, and amendments thereto, shall be made on a form prescribed and furnished by the Board. Applications for registration shall contain such information as may be required by the Board in accordance with the provisions of K.S.A. 65-1655, and amendments thereto.

2. Pursuant to K.S.A. 65-1643(e), it shall be unlawful for any person to distribute or dispense samples of any drugs without first obtaining a registration from the Board.

3. The Board's application for registration as a sample distributor requires Applicant provide 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, and a copy of the products intended to be shipped into Kansas.

4. Applicant failed to provide the following in conjunction with Applicant's Application: Applicant's detailed ownership information, a list of other states where Applicant is registered, and list of the drug samples being distributed.

5. Applicant's failure to provide the Board with the required application information constitutes an incomplete application and is a basis to deny Applicant's Application.

6. Additionally, Applicant failed, after emails and letters from the Board, to provide the lawfully requested application information.

ORDER

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

NOTICES

Respondent is hereby notified as follows:

1. 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 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

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 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 K.S.A. 77-613. 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.

10/12/2021

Date

Mars Blasi

Alexandra Blasi, JD, MBA Executive Secretary Kansas Board of Pharmacy

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CERTIFICATE OF SERVICE

I hereby certify that I did, on the 12th day of October 2021, 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:

Merz North America, Inc. 13900 W Grandview Parkway Sturtevant WI 53177

Alex Blasi

Kansas Board of Pharmacy Staff