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Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

August 9, 2021

Attn: Anil Peter
Luya Pharma USA Ltd
502 Carnegie Center, Suite 100
Princeton NJ 08540

RE: Case No. 21-141

Dear Anil Peter:

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

In the Matter of)
)
Luye Pharma USA Ltd)
)
Respondent No. 5-113074)

Case No. 21-141

KANSAS STATE
BOARD OF PHARMACY

SUMMARY ORDER OF DENIAL

NOW, on this 9th day of August 2021, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Secretary, the matter of Luye Pharma USA Ltd ("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 August 24, 2020, the Board received Applicant’s application for registration as a wholesale distributor in the State of Kansas (“Applicant’s Application”).
2. On October 7, 2020, the Board sent Applicant an email requesting several required information items that were missing from Applicant’s Application.
3. On March 2, 2021, the Board sent Applicant a second email requesting required information which was still missing from Applicant’s Application, specifically a list of facilities Applicant is transacting business with, a list of products Applicant was planning to ship into Kansas, other state registrations, past experience statement, a list of trade or business names, a surety bond, and detailed ownership information.

4. On May 6, 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.

5. To date, the Board has not received the required application documents or any further correspondence from Applicant.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1627(f)(8), the Board may deny the application of any wholesale distributor upon a finding that the wholesale distributor has failed to furnish to the Board any information legally requested by the Board.

2. 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.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Pursuant to K.S.A. 65-1655(a), the Board shall require an applicant for registration as a wholesale distributor or an applicant for renewal of such a registration to provide the following information: (1) the name, full business address and telephone number of the applicant; (2) all trade or business names used by the applicant; (3) addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling and distribution of prescription drugs; (4) the type of ownership or operation of the applicant; (5) the name of the owner or operator, or both; and (6) such other information as the Board deems appropriate.

5. Pursuant to K.S.A. 65-1655(c), the Board may deny an initial application for registration or application for renewal of a registration of a wholesale distributor if the Board

determines that the granting of such registration would not be in the public interest.

6. The Board's application for registration as a wholesale 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.

7. Applicant failed to provide the following in conjunction with Applicant's Application: a list of facilities Applicant is transacting business with, a list of products Applicant was planning to ship into Kansas, other state registrations, experience statement, a list of trade or business names, a surety bond, and detailed ownership information.

8. Applicant's failure to provide the Board with the required application information is a basis to deny Applicant's Application pursuant to K.S.A. 65-1645(a) and 65-1655(a) and (c).

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

10. Applicant's failure to supply the Board with the requested documentation is a basis to deny Applicant's Application pursuant to K.S.A. 65-1627(f)(8).

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.

8/9/2021
Date



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

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 9th day of August 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:

Luye Pharma USA Ltd
502 Carnegie Center, Suite 100
Princeton NJ 08540



Kansas Board of Pharmacy Staff