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Topeka, KS 66612



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www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

August 9, 2021

Attn: Ian Liu  
Breas Medical Inc  
16 Esquire Rd  
North Billerica MA 01862

RE: Case No. 21-144

Dear Ian Liu:

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](mailto:Pharmacy.Compliance@ks.gov).

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

Filed By

AUG 9 2021

KANSAS STATE BOARD OF PHARMACY

Case No. 21-144

In the Matter of )  
 )  
Breas Medical, Inc. )  
 )  
Applicant )

**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 Breas Medical, 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 October 29, 2020, the Board received Applicant's application for registration as a wholesale distributor in the State of Kansas ("Applicant's Application").
2. On January 20, 2021, the Board sent Applicant an 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 other trade or business names, detailed ownership information, a list of other state registration numbers, a surety bond, a statement of experience, a list of products planned to be shipped into Kansas, and an inspection report.
3. On April 28, 2021, the Board sent a final letter to Applicant's address of record requesting the above information and providing a response deadline of May 31, 2021.

4. 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. Pursuant to K.S.A. 65-1655(f), each wholesale distributor must undergo an inspection

by the board or a third party recognized by the board to inspect wholesale distributors for the purpose of inspecting the wholesale distribution operations prior to initial registration and not less than once every three years thereafter.

7. The Board's application for registration as a wholesale distributor requires Applicant provide the most recent inspection report conducted within the past three years 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, and a copy of the products intended to be shipped into Kansas.

8. Applicant failed to provide the following in conjunction with Applicant's Application: a list of facilities Applicant is transacting business with, a list of other trade or business names, detailed ownership information, a list of other state registration numbers, a surety bond, a statement of experience, a list of products planned to be shipped into Kansas, and a valid inspection report.

9. 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), (c), and (f).

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

11. 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

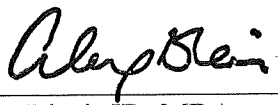
Respondent is hereby notified as follows:

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.

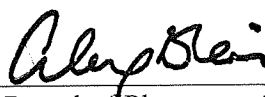
8/9/2021  
Date

  
\_\_\_\_\_  
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:

Breas Medical, Inc.  
16 Esquire Rd  
North Billerica MA 01862



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Kansas Board of Pharmacy Staff