

December 18, 2023

Virtus Pharmaceuticals, LLC
310 George Patterson Dr, Ste 104A
Bristol PA 19047

RE: Case No. 23-465

To Who 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

PABEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of)	
)	Case No. 23-465
Virtus Pharmaceuticals, LLC)	
)	
)	
<u>Applicant</u>)	

SUMMARY ORDER OF DENIAL

NOW, on this 18th day of December 2023, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Secretary, the matter of Virtus Pharmaceuticals, LLC ("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 July 18, 2023, the Board received Applicant’s application for registration as a manufacturer in the State of Kansas (“Applicant’s Application”).
2. On July 19, 2023, the Board sent Applicant an email requesting required information items that were missing from Applicant’s Application.
3. On August 15, 2023, the Board sent Applicant a second email requesting the required information items that was still missing from Applicant’s Application.
4. On September 15, 2023, the Board sent Applicant a third email requesting the required information items that were still missing from Applicant’s Application.
5. On October 20, 2023, the Board sent a final letter to Applicant’s address of record

requesting the required information items that were still missing from Applicant's Application, specifically, satisfactory FDA inspections completed within the past 3 years for two contract manufacturers (Catalent Pharma Solutions and Epic Pharma LLC), and providing a response deadline of November 30, 2023.

6. 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 manufacturer upon a finding that the manufacturer 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. 65-1643d, and amendments thereto.

3. Pursuant to K.S.A. 65-1643(p), it shall be unlawful for any person to distribute drugs or devices into Kansas as an out-of-state manufacturer of such drugs or devices without first obtaining a registration as a manufacturer from the Board.

4. Pursuant to K.S.A. 65-1643d, the Board shall require an applicant for registration as a manufacturer 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) all 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 or devices; (4) the type of ownership or operation of the applicant; (5) the name

of the owner or operator of the applicant, including; (A) If an individual, the name of the individual; (B) if a partnership, the name of each partner and the name of the partnership; (C) if a corporation, the name and title of each corporate officer and director of the corporation and the name of the state of incorporation; or (D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and (6) any other information as the Board deems appropriate.

5. Pursuant to K.S.A. 65-1643d(f), each facility that manufactures drugs or devices shall undergo an inspection by the board or a third party recognized by the board prior to initial registration and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three years.

6. Applicant failed to provide the following in conjunction with Applicant's Application: satisfactory FDA inspections completed within the past 3 years for two contract manufacturers (Catalent Pharma Solutions and Epic Pharma LLC). 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).

7. 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.

12/18/2023

Date




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

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 18th day of December 2023, 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:

Virtus Pharmaceuticals, LLC
310 George Patterson Dr, Ste 104A
Bristol PA 19047



Kansas Board of Pharmacy Staff