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Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

January 8, 2024

Chemocentryx Inc.  
835 Industrial Road, Suite 600  
San Carlos CA 94070

RE: Case No. 24-001

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

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 24-001
Chemocentryx Inc.	)	
	)	
<u>Applicant</u>	)	

**SUMMARY ORDER OF DENIAL**

NOW, on this 8th day of January 2024, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Secretary, the matter of Chemocentryx Inc. ("Respondent").

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. The Board had previously issued Respondent Registration No. 4-114951 which entitled Respondent to operate as a manufacturer in the state of Kansas.
2. On July 25, 2023, the Board received from Respondent a Form BA-04 Manufacturer Registration Application, notifying of change in ownership and applying for a new manufacturer registration under the new ownership. Upon further inquiry, Respondent indicated the ownership change transaction date was October 20, 2022.
3. On July 26, 2023, the Board sent Respondent an email requesting required information items that were missing from Respondent’s Application.
4. On August 22, 2023, the Board sent Respondent a second email requesting the

required information items that was still missing from Respondent's Application.

5. On September 19, 2023, the Board sent Respondent a third email requesting the required information items that were still missing from Respondent's Application.

6. On October 20, 2023, the Board sent Respondent a fourth email requesting the required information items that were still missing from the Respondent's application.

7. On November 22, 2023, the Board sent a final letter to Respondent's address of record requesting the required information items that were still missing from Respondent's Application, specifically, clarification of requirement to be registered in home state (conflicting information in application) and a satisfactory inspection of the virtual manufacturer office within the past 3 years, and providing a response deadline of December 31, 2023.

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

#### 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(f), any registration issued under K.S.A. 65-1643, and amendments thereto, shall not be transferable.

3. 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.

4. 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.

5. The Board's application for registration as a manufacturer requires copy of current registration or permit issued by state of residence, list of other states in which registered (with permit numbers), S-350 Non-Resident Information form, S-300 Disciplinary History form and explanation documents if any Discipline Information questions are answered "yes", S-310, S-320 or S-330 ownership forms and/or business organization chart, along with supporting ownership documents (refer to top of individual forms for requirement), facility inspection report conducted at current physical location within the past 3 years by state of residence, NABP, or FDA. In addition to all requirements listed above, virtual manufacturers must provide a list of all contract manufacturers with name, address, email address, and FEI number, a list of all products manufactured.

6. Respondent failed, after multiple emails and a letter from the Board, to provide the following in conjunction with Respondent's Application: clarification of requirement to be registered in home state (conflicting information in application) and a satisfactory inspection of the virtual manufacturer office within the past 3 years.

7. Respondent's failure to submit a complete ownership change application to the Board until July 25, 2023 – 7 months after the change – indicates that Respondent was operating under a manufacturer registration issued to another owners, which is a transfer of the registration in violation of K.S.A. 65-1645(f).

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

## **ORDER**

Based upon the foregoing findings of fact and conclusions of law, Respondent'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.

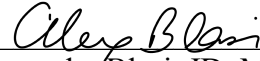
4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi  
Executive Secretary  
Kansas Board of Pharmacy  
800 SW Jackson, Suite 1414  
Topeka, KS 66612

IT IS SO ORDERED.

1/8/2024

Date




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

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 8th day of January 2024, 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:

Chemocentryx Inc.  
835 Industrial Road, Suite 600  
San Carlos CA 94070

  
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Kansas Board of Pharmacy Staff