

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



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

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

June 12, 2023

Mark Robert Fedele
Eugia US LLC
279 Princeton Hightstown Road, Suite 214
East Windsor NJ 08520

RE: Case No. 23-259

Dear Mr. Fedele:

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

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of)
)
Eugia US LLC.)
)
Applicant)

Case No. 23-259

SUMMARY ORDER

NOW on this 12th day of June 2023, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Director, the matter of Eugia US LLC (“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 Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board’s Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board had previously issued Respondent Registration No. 4-118004 which entitled Respondent to operate as a manufacturer in the State of Kansas.
2. On April 1, 2022, the ownership of Respondent’s facility changed from AuroMedics Pharma LLC to Eugia Inc.
3. On October 26, 2022, the Board received written notification of the ownership change by email from State License Servicing, Inc.
4. On March 29, 2023, the Board received from Respondent a Form BA-04 Manufacturer Registration Application, notifying of the change in ownership effective April 1, 2022, and applying for a new manufacturer registration under the new ownership.

5. On June 6, 2023, Respondent confirmed that the most recent FDA inspection for its single contract manufacturer, Eugia Pharma Specialties Limited, was completed in December of 2018, which is 4 ½ years ago.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration to manufacture drugs or devices upon a finding that the registrant has violated the Kansas Pharmacy Practice Act or rules and regulations adopted thereunder.

2. Pursuant to K.S.A. 65-1643(g), it shall be unlawful for any person to manufacture any drugs or devices without first obtaining a registration to do so from the Board.

3. Pursuant to K.S.A. 65-1645(f), any registration issued under K.S.A. 65-1643, and amendments thereto, shall not be transferable.

4. Pursuant to K.S.A. 65-1643d(c), the Board may deny an initial application for registration or application for renewal of a registration if the Board determines that the granting of such registration would not be in the public interest.

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. Pursuant to K.S.A. 65-1643d(g), the Board may register a manufacturer or virtual manufacturer that is licensed or registered under the laws of another state if the requirements of that state are deemed by the Board to be substantially equivalent to the requirements of this state.

7. Applicant's failure to submit the complete ownership change application to the Board until March 29, 2023 – almost one full year after the change – indicates that Respondent

was operating under a manufacturer registration issued to another owner, which is a transfer of the registration in violation of K.S.A. 65-1645(f).

8. In conjunction with Applicant's Application, Applicant only provided an inspection report from December 2018, more than four years old. Applicant failed to provide the Board with a current contract manufacturer inspection within the past three years, which is a violation of K.S.A. 65-1643d(f) and a basis to deny Applicant's Application for being incomplete and failing to meet the requirements for registration pursuant to K.S.A. 65-1627(f).

ORDER

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

NOTICES

The Respondent is hereby notified as follows:

1. The 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 fifteen (15) days after service of this order.

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 fifteen (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 said statute. 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.

6/12/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

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

Mark Robert Fedele
Eugia US LLC
279 Princeton Hightstown Road, Suite 214
East Windsor NJ 08520



Kansas Board of Pharmacy Staff