

May 25, 2023

Elena Learner
2440 Research Blvd.
Rockville MD 20850

RE: Case No. 23-252
Otsuka America Pharmaceutical Inc.

Dear Ms. Learner:

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. In addition, a civil fine has been assessed totaling \$1,740. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

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 STATE BOARD OF PHARMACY

In the Matter of)	
)	Case No. 23-252
Otsuka America Pharmaceutical, Inc.)	
)	
<u>Registration Number 4-120630</u>)	

SUMMARY ORDER

NOW, on this 25th day of May 2023, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Secretary, the matter of Otsuka America Pharmaceutical, Inc.. ("Applicant"), for application for registration as a manufacturer in the state of Kansas.

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 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 May 17, 2023, the Board received Applicant’s application for registration as a manufacturer in the State of Kansas (“Applicant’s Application”).
2. On Applicant’s Non-Resident Supplemental S-350 form, Applicant answered “Yes” to the following question: “Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months.” The form directs that if the applicant answered “yes,” the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas.”
3. In conjunction with Applicant’s Application, Applicant provided requested copies of

shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 37 unique days during the previous 12-month period.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed \$5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f)(6), the Board may take action against the application of any manufacturer provider upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. 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 from the Board.

4. Applicant's act of operating in Kansas prior to being registered as a manufacturer is a violation of K.S.A. 65-1643(g) and is a basis to take action against Applicant's Application pursuant to K.S.A. 65-1627(f)(6).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of \$1,740. Applicant has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt.

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.

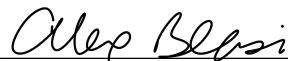
4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

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

IT IS SO ORDERED.

5/25/2023

Date

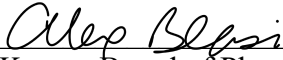


Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 25th day of May 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:

Elena Learner
Otsuka America Pharmaceutical, Inc.
2440 Research Blvd.
Rockville MD 20850



Kansas Board of Pharmacy Staff