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Kansas
Board of Pharmacy

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Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

September 3, 2024

Impladent Ltd
86-90 188th St
Jamaica NY 11423

RE: Case No. 24-271

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.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 24-271
Impladent Ltd	)	
	)	
	)	
Registration Number 4-122219	)	

SUMMARY ORDER OF DENIAL

NOW, on this 3rd day of September, 2024, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Impladent Ltd ("Respondent"), for renewal of the non-resident manufacturer registration issued by the Board.

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 has previously issued Respondent Registration No. 4-122219 which entitles Respondent to operate as a non-resident manufacturer in the State of Kansas ("Respondent's Registration").

2. On June 13, 2024, the Board received Respondent's online application for renewal of Respondent's Registration ("Respondent's Application").

3. On June 16, 2024, the Board sent Registrant an email requesting several required information items that were missing from Respondent's Application.

4. On June 27, 2024, the Board sent Respondent a second email requesting the required

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

5. On July 15, 2024, the Board sent a final letter and email to Respondent's address of record requesting the required information items that were still missing from Respondent's Application, specifically, Respondent's customer list and a copy of a satisfactory inspection for the facility, and providing a response deadline of July 30, 2024.

6. To date, the Board has not received the required renewal 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 renewal 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(c), the Board may deny an initial application for registration or application for renewal of a registration of a manufacturer if the Board determines that the granting of such registration would not be in the public interest.

6. 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.

7. The Board's renewal 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, (for virtual manufacturers, if home state does not routinely inspect virtual office, submit N-300 Self-Attestation form and I-04 Manufacturer Self-Inspection form). 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.

8. Respondent failed to provide the following in conjunction with Respondent's Application: Respondent's customer list and a copy of a satisfactory inspection for the facility. Respondent's failure to provide the Board with the required renewal application information is a basis to deny Respondent's Application pursuant to K.S.A. 65-1645(a) and 65-1627(a).

9. Respondent failed, after multiple emails and letter from the Board, to provide the lawfully requested renewal application information.

10. 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.

9/3/2024
Date

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

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 3rd day of September, 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:

Impladent Ltd
86-90 188th St
Jamaica NY 11423

Kansas Board of Pharmacy Staff