

May 20, 2022

Linde Gas & Equipment Inc  
9 Judith Lane  
Cahokia IL 62206

RE: Case No. 22-072

To whom it may concern:

Enclosed you will find an Amended 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 \$3,480. 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](mailto:Pharmacy.Compliance@ks.gov).

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-072
Linde Gas & Equipment Inc.	)	
	)	
<u>Registration 4-1177555</u>	)	

**AMENDED SUMMARY ORDER**

NOW, on this 20th day of May 2022, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Secretary, the matter of Linde Gas & Equipment Inc ("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 Amended 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 October 27, 2021, the Board received Applicant’s application for registration as a wholesale distributor in the State of Kansas (“Applicant’s Application”).
2. On November 1, 2021, the Board sent Applicant an email requesting several required information items that were missing from Applicant’s Application.
3. On November 30, 2021, the Board sent Applicant a second email requesting required information which was still missing from Applicant’s Application, specifically an inspection report.
4. On January 12, 2022, the Board sent a final letter to Applicant’s address of record requesting the above information and providing a response deadline of February 15, 2022.
5. On April 1, 2022, the Board received the requested information from Applicant as

well as an updated Application, this time correctly for a manufacturer registration instead of a wholesale distributor registration.

6. 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."

7. In conjunction with Applicant's Application, Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 124 unique days during the previous 12-month period.

8. In conjunction with Applicant's Application, Applicant provided an N-300 and 1-04 Self Inspection form for the facility, but did not provide any other inspection report for the facility.

#### 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 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. 65-1627(f)(8), the Board may action against 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.

4. 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.

5. 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. 65-1655, and amendments thereto.

6. Pursuant to K.S.A. 65-1643d, the Board shall require an applicant for registration as a manufacturer or virtual 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) 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; (4) the type of ownership or operation of the applicant; (5) the name of the owner or operator, or both; and (6) such other information as the Board deems appropriate.

7. Pursuant to K.S.A. 65-1643d(f), each manufacturer must undergo an inspection by the board or a third party recognized by the board to inspect manufacturers for the purpose of inspecting the facility operations prior to initial registration and not less than once every three years thereafter.

8. The Board's application for registration as a manufacturer requires Applicant provide the most recent inspection report conducted within the past three years by the state of residence, FDA, or the National Association of Boards of Pharmacy, detailed ownership information, information concerning any disciplinary history for the facility, proof of valid registration in the state of residence, information concerning any permits held in other states, and a copy of the products intended to be manufacturer for Kansans.

9. Applicant only provided a self-inspection report in conjunction with Applicant's Application.

10. Applicant's failure to provide the Board with the required inspection is a basis to take action against Applicant's Application pursuant to K.S.A. 65-1645(a) and 65-1643d.

11. Applicant's activity in Kansas prior to being registered as a manufacturer is a violation of K.S.A. 65-1643(c) and 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 \$3,480. Applicant has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt. In addition, Applicant is required to provide the Board with a satisfactory inspection report from Applicant's resident state, NABP, or FDA prior to the 2023 renewal application but no later than June 30, 2023, whichever is earlier.

### **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.

5/20/2022

Date



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

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 20th day of May 2022, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Linde Gas & Equipment Inc  
9 Judith Lane  
Cahokia IL 62206



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Kansas Board of Pharmacy Staff