IN THE MATTER OF	*	**BEFORE THE**
IZEEN PHARMA, INC.	*	**STATE BOARD OF**
RESPONDENT-DISTRIBUTOR	*	**PHARMACY**
PERMIT NO.: D06251	*	**CASE NO.: 18-050 & 19-223**

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FINAL ORDER OF REVOCATION OF WHOLESALE DISTRIBUTOR PERMIT

On June 19, 2019, the State Board of Pharmacy (the "Board") notified Izeen Pharma, Inc. ("Respondent-Distributor"), permit number: D06251 of the Board's intent to revoke its permit to engage in wholesale distribution under the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") §§ 12-101 et seq. (2014 Repl. Vol. and 2018 Supp.). The pertinent provisions of the Act and the regulations state:

Health Occ. § 12-601. Disciplinary actions.

(a) *In general* - Subject to the hearing provisions of § 12–315 of this title, for a violation of this subtitle, Subtitle 6C of this title, or any regulation adopted under Subtitle 6C of this title, the Board may:

(1) Deny a permit to an applicant;
(2) Reprimand a permit holder;
(3) Place a permit holder on probation; or
(4) Suspend or revoke a permit.

Health Occ. §12–6C–03. Permit required.

(a) A wholesale distributor shall hold a permit issued by the Board before the wholesale distributor engages in wholesale distribution in the State.

The Board also charges the Respondent-Distributor with violating:

COMAR 10.34.22

.10 Required Information and Procedures for Ceasing to Operate.

B. Procedures for Wholesale Distributors Located in this State for Ceasing to Operate.

(1) Notification.

(a) At least 30 days before a wholesale distributor's anticipated date of ceasing to operate, the wholesale distributor shall notify the Board in writing, by certified mail, return receipt requested, or hand delivered to the Board's office, of the day on which the wholesale distributor will cease to operate.

(b) A wholesale distributor shall:

(i) Notify drug and device suppliers that supply prescription drugs and devices to the wholesale distributor, at least 30 days in advance of ceasing to operate, of the date that the wholesale distributor will cease to operate;

(ii) Notify manufacturers, wholesale distributors, licensed pharmacies and authorized prescribers that receive prescription drugs and devices from the wholesale distributor, at least 30 days in advance of ceasing to operate, of the date that the wholesale distributor will cease to operate; and

(iii) Comply with applicable federal regulations.

(2) The wholesale distributor shall submit to and pass a closing inspection conducted by the Board.

(3) With the exception of controlled dangerous substances, the wholesale distributor shall dispose of prescription drugs or devices in stock by one or more of the following means:

(a) Returning the prescription drugs or devices to a distributor or manufacturer;

(b) Transferring the prescription drugs or devices to another wholesale distributor, licensed pharmacy, authorized prescriber, or other person or entity approved by the Board; or

(c) Destroying in accordance with this regulation.

FININDGS OF FACT

1. The Respondent-Distributor was originally issued a permit to engage in wholesale distribution, under permit number D06251 on November 22, 2017. The Respondent- Distributor's permit number D06251 expired on May 31, 2019.

2. On or about October 17, 2017, the Board received a complaint from a representative for a corporation ("Corporation A") located in Florida.[1]

3. The complaint alleged that the Respondent-Distributor manufactured and distributed a combination product containing levothyroxine and liothyronine ("Thyroid Tablets, USP") without a permit. The complaint also alleged that the Respondent-Distributor continued manufacturing and distributing Thyroid Tablets, USP after the medication was recalled by Corporation A because of risks of adulteration.

4. An investigation conducted by Board staff revealed that between September 2017 and June 2018, the Respondent-Distributor manufactured and distributed millions of Thyroid Tablets, USP in various strengths, to Corporation B, a repackaging company, located in Alabama. The repackaged Thyroid Tablets, USP were then shipped to Corporation A.

5. On or about August 20, 2018, Corporation A recalled Thyroid Tablets, USP with various dosage amounts manufactured and distributed by the Respondent-Distributor, and repackaged by Corporation B, between October 2017 and August 2018.

6. Thirty-seven (37) of the thirty-eight (38) batches of Thyroid Tablets, USP recalled by Corporation A had been manufactured and distributed by the Respondent-

[1] The names of Corporation A and Corporation B have been omitted to protect privacy.

Distributor.

7. On or about January 19, 2019, a Board inspector, during normal business hours arrived at the Respondent-Distributor located in Fredrick County, Maryland to conduct a Bi-Annual Distributor inspection.

8. Upon arrival at the Respondent-Distributor, the inspector noticed that the inside of Respondent-Distributor was dark, unoccupied, and appeared to be no longer operational. The inspector also noticed that there were no vehicles in the adjacent parking lot.

9. The inspector attempted to contact the permit-holder of the Respondent-Distributor by telephone but was unsuccessful. The inspector also left the permit-holder a voice message informing the permit-holder that she was at the Respondent-Distributor.

10. The inspector observed court county documents posted on the door of the Respondent-Distributor. One document stated that property inside of the Respondent-Distributor "had been attached and in the custody of the sheriff of Frederick County Maryland". The other document was a writ of execution from the clerk of the circuit court for Frederick County, Maryland.

11. The permit-holder of the Respondent-Distributor did not inform the Board that the Respondent-Distributor was no longer operating as a wholesale distributor.

12. The Respondent-Distributor violated the Act and the regulations thereunder when it operated without a permit; manufactured and distributed Thyroid Tablets, USP after a recall; and ceased operating as a wholesale distributor without following procedures

required by the Board.

CONCLUSIONS OF LAW

The Board concluded that the Respondent-Distributor violated Health Occ. § 12-6C-03 and COMAR 10.34.22.10B (1), (2), and (3).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, a quorum of the Board, hereby:

ORDERED that the Respondent-Distributor's permit to operate as a wholesale distributor in the State of Maryland is hereby **REVOKED**; and it is further

ORDERED that Respondent shall return to the Board of Pharmacy all Maryland permits within ten (10) days of the date of this Order; and it is further.

ORDERED that the effective date of this Order is the date that it is signed by the Board; and it is further

ORDERED that this Order is final and a public document pursuant to Md. Code Ann., General Provisions §§ 4-104 *et seq*. (2014 Repl. Vol and 2018 Supp); and it is further

ORDERED that this Order is reportable to the National Practitioner Bank; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Board of Pharmacy and is a public document for purposes of public disclosure, pursuant to Md. Code Ann., General Provisions §§ 4-101 *et seq*. (2014 Repl. Vol and 2018 Supp.).

9/18/19
Date

Kevin Morgan, Pharm.D.
President
State Board of Pharmacy