IN THE MATTER OF	*	**BEFORE THE**
NUO THERAPEUTICS, INC.	*	**MARYLAND BOARD**
Respondent-Distributor	*	**OF PHARMACY**
DISTRIBUTOR PERMIT NO.: D06158	*	**Case No.: 22-002**

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FINAL ORDER

On the 27th day of January, 2022, the Maryland Board of Pharmacy (the "Board") notified **NUO THERAPEUTICS, INC.** ("the Respondent-Distributor"), Distributor Permit Number D06158, of its intent to revoke its distributor permit pursuant to the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2021 Repl. Vol.) and certain provisions of the Board's regulations found at Md. Code Regs. ("COMAR") 10.34 *et seq.*

Specifically, the Board based its action on the Respondent's violation of the following provisions of the Act:

Health Occ. § 12-6C-03. Permit requirements; wholesale distributors.

(b)(1) A manufacturer engaged in wholesale distribution shall hold a wholesale distributor permit issued under this subtitle.

Health Occ. § 12-6C-06. Expiration, renewal of permits.

(b)(8) The Board may deny, suspend, or revoke the permit of a wholesale distributor if the Board determines that the wholesale distributor no longer qualifies for a permit.

Health Occ. § 12-6C-07. Inspections.

The Board:

(1) Shall adopt regulations that require routine inspections of wholesale distributor facilities[.]

The pertinent provisions of COMAR 10.34 provide as follows:

COMAR 10.34.22.03 Minimum Application Requirements for Applicants Holding Product.

I. The wholesale distributor shall provide changes in information provided pursuant to Regulation .03 of this chapter to the Board within 30 days of the effective date of the change.

COMAR 10.34.22.05 Violations and Penalties.

A. After a hearing held under Health Occupations Article, § 12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

. . . .

(3) Commits any of the following acts:

. . . .

(d) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

. . . .

(v) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law[.]

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[.]

. . . .

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

. . . .

(5) At the closing inspection, the wholesale distributor shall provide to the Board the following:

(a) The exact date on which the wholesale distributor ceased to operate;

(b) A copy of the inventory of prescription drugs or devices disposed of, transferred, or returned.

(c) The names, addresses, telephone numbers, and Drug Enforcement Administration registration numbers, if applicable, of the persons or business entities to whom prescription drugs or devices in stock were returned or transferred under this regulation;

(d) The wholesale distributor permit;

(e) If prescription drugs or devices are destroyed pursuant to this regulation, a letter, signed under oath by the wholesale distributor, stating the:

(i) Date, place and manner in which the prescription drugs or devices were destroyed;

(ii) Names, addresses, and telephone numbers of the persons responsible for destroying the prescription drugs or devices; and

(iii) Name, dosage unit, and quantity of each type of prescription drug or device destroyed; and

(f) If any pedigrees or other documents are transferred, a letter, signed under oath by the wholesale distributor, stating:

(i) The date, time, place to which and manner in which the pedigrees or other documents were transferred; and

(ii) The names, addresses, and telephone numbers

of the persons responsible for transferring the pedigrees or other documents[.]

COMAR 10.34.22.11 Relocation.

A. At least 30 days before relocation, a permit holder shall submit an application to the Board.

B. If relocation is due to a catastrophic event or State of Emergency, the relocation applicant shall:

(1) Notify the Board within 48 hours; and

(2) Submit an application to the Board within 30 days.

C. A relocation applicant:

(1) If the applicant holds products, shall comply with Regulation .07 of this chapter;

(2) Shall submit a surety bond or other equivalent means of security acceptable to the State specific to the permit holder's relocation, in accordance with Regulation .03 of this chapter; and

(3) Shall indicate on the application changes in product or personnel from the original application to the Board.

COMAR 10.34.30.04. Applications for Pharmacy or Wholesale Distributor Establishment Change of Location.

A. Permits issued to operate a pharmacy or engage in wholesale distribution, whether located in the State or outside the State, are:

(1) Not transferable; and

(2) Specific to the establishment location that has undergone an opening inspection by the Board.

B. A pharmacy or wholesale distributor that intends to change its establishment location shall:

(1) Submit an application to the Board on a form required by the Board;

(2) If located in the State, comply with opening and closing inspection requirements in order to:

(a) Commence operations at the new establishment location; and

(b) Cease operations at the existing establishment location; and

(3) If located outside the State, submit an inspection report for the new location conducted by the authorized entity in the state in which the establishment is located, or provide documentation of supplemental accreditation, if applicable.

COMAR 10.34.30.05. Change of Information Provided in Applications.

Notwithstanding any other reporting requirements, a permit holder shall provide written notification to the Board at least 30 days prior to any change in information in its application provided to the Board, to include:

A. Change in hours of operation; or

B. Change in the physical structure of the establishment, to include any:

(1) Deviation from the floorplan submitted by the permit holder as part of the application; or

(2) Other change that may affect the security or storage conditions of prescription drugs or devices.

In its Notice, the Board informed the Respondent-Distributor that it had the opportunity to request a hearing before the Board by submitting a request in writing to the Board's Executive Director within thirty days of service of the Notice. More than thirty days have elapsed since the service of the Notice on the Respondent-Distributor, and the Respondent-Distributor has not requested a hearing.

FINDINGS OF FACT

The Board makes the following findings of fact:

1. At all times relevant hereto, the Respondent-Distributor had a permit to operate as a manufacturing distributor in the State of Maryland. The Respondent-Distributor

was originally issued a permit on or about June 1, 2017. The Respondent-Distributor's permit expired on May 31, 2021.

2. At all times relevant, the Respondent-Distributor operated as a manufacturer of prescription Class I[1] medical devices[2] located in Montgomery County, Maryland.

3. On or about June 14, 2021, a Board inspector attempted to contact the Respondent-Distributor via their telephone number of record with the Board. According to the Board inspector's call logs, the telephone number of record rang busy and would not allow the caller to leave a message.

4. On or about June 14, 2021, a Board inspector attempted to contact the Respondent-Distributor via the email address of record with the Board. The email bounced back as "undeliverable."

5. On or about June 16, 2021, a Board inspector arrived at the Respondent-Distributor's physical address of record with the Board.[3] The Board inspector was unable to locate the Respondent-Distributor.

6. According to the Board's records, the last Board-initiated on-site distributor inspection occurred on or about January 31, 2019. Since that time, there has not been any correspondence or notification from the Respondent-Distributor alerting

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[1] The FDA classifies all medical equipment into three (3) classes based on risk to the public. Class I devices are low-risk devices. Examples include bandages, handheld surgical instruments, and nonelectric wheelchairs.

[2] According to the Respondent-Distributor's SEC Filings, "Nuo Therapeutics, Inc. is a biomedical company that pioneers leading-edge biodynamic therapies for wound care. The Company's flagship product, Aurix is a biodynamic hematogel that harnesses a patient's innate regenerative abilities for the management of a variety of wounds." (Retrieved on 1/4/2022 from: https://sec.report/CIK/0001091596)

[3] On their May 13, 2019, renewal application, the Respondent-Distributor paid with a business check that listed a different physical address. The Board's inspector also visited this location and was unable to locate the Respondent-Distributor.

the Board of their relocation or closure.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Distributor's actions constitute violations of: Health Occ. § 12-6C-03, Health Occ. § 12-6C-06, Health Occ. § 12-6C-07, COMAR 10.34.22.03, COMAR 10.34.22.05, COMAR 10.34.22.10, COMAR 10.34.22.11, COMAR 10.34.30.04, and COMAR 10.34.30.05.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is, by the affirmative vote of a majority of the Board considering this case:

ORDERED that the Respondent-Distributor **NUO Therapeutics, Inc.'s** permit to distribute prescription Class I medical devices in the State of Maryland under Distributor Permit Number **D06158** be and hereby is **REVOKED**; and it is further

ORDERED that this Order is a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 *et seq.* (2014).

10/19/22
Date

Jennifer L. Hardesty, Pharm.D.
President
Maryland Board of Pharmacy

NOTICE OF RIGHT TO APPEAL

Pursuant to Md. Code Ann., Health Occ. § 6-310(b) (2021 Repl. Vol.), you have a right to take a direct judicial appeal. A Petition for Judicial Review must be filed within thirty (30) days of service of this Order and shall be made as provided for judicial review

of a final decision in the Md. Code Ann., State Gov't §§ 10-201 *et seq.* (2021 Repl. Vol.) and Title 7, Chapter 200 of the Maryland Rules.