

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

Maryland Board of Pharmacy

Kristopher Rusinko, PharmD, MBA, M.Ed., MS, Board President Deena Speights-Napata, M.A., Executive Director 4201 Patterson Avenue Baltimore, MD 21215-2299

October 18, 2024

VIA REGULAR, EMAIL & CERTIFIED MAIL RETURN RECEIPT REQUESTED ARTICLE#: 7019 2280 0000 6558 0085

Biologics Unlimited dba Allograts.com c/o Nikki Couloumbis, Owner 19 Greenspring Valley Road Garrison, Maryland 21117

Re: Permit No. D05881 (non-renewed)

Case No. 24-359

Notice of Deficiencies, Imposition of Civil Monetary Penalty, and

Opportunity for Hearing

Dear Mr. Couloumbis:

The Maryland Board of Pharmacy's (the "Board") records indicate that Biologics Unlimited dba Allograts.com (the "Distributor") allowed its Maryland wholesale distributor permit to lapse on May 31, 2023, for its distribution facility located in Ellicott City, Maryland. The Board's inspector subsequently visited the facility location and noted that the Distributor was no longer there and no signage for the Distributor was present. The Board was not given notice of the Distributor's closure, nor did the Distributor undergo a closing inspection and provide the Board with documentation regarding the disposition of its prescription inventory in accordance with COMAR 10.34.22.10.

I. FINDINGS AND CONCLUSION

The Board finds that the Distributor ceased operations without due notice to the Board of Pharmacy, and failed to undergo a closing inspection to verify the disposition of prescription inventory, in violation of the Maryland Pharmacy Act.

Based upon the Distributor's failure to file proper notice of closure and failure to submit to a closing inspection, the Board finds that the Distributor is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Distributor in violation of Health Occ. Art. § 12-6C-12 and COMAR 10.34.22.10.

II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-6C-11 and COMAR 10.34.22.05, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the Distributor's violations noted above, the Board hereby recommends the imposition of a civil monetary penalty of \$500.00.

In determining the recommended civil monetary penalty, the Board took into consideration the factors set forth in Health Occ. § 12-6C-11(a)(2) and COMAR 10.34.11.08.

III. FOLLOW-UP ACTION REQUIRED

Please be advised that the Distributor shall submit: (1) a copy of the inventory of prescription drugs, including controlled dangerous substances, disposed of, transferred, or returned; (2) names, contact information, and DEA numbers of persons or entities to whom prescription drugs were transferred; (3) original wholesale distributor permit; and (4) controlled dangerous substances permit, if applicable.

IV. OPPORTUNITY FOR HEARING

If the Distributor disputes the findings, conclusions or the civil monetary penalty, the Distributor may request an evidentiary hearing on the Board's decision in this matter. In the event that the Distributor requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 *et seq.*, and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Trina Leak, Pharm.D., Compliance Director, Maryland Board of Pharmacy, 4201 Patterson Ave., 5th Floor, Baltimore, Maryland 21215, **no later than thirty (30) days of the date of this Notice.**

Please be advised that at the hearing the Distributor would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on its own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Distributor in violation of the

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Maryland Pharmacy Act, the Board may reprimand, suspend or revoke the distributor permit, place the permit on probation, and/or impose civil penalties. If the Distributor requests a hearing but fails to appear, the Board may nevertheless hear and determine the matter in its absence.

V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Distributor may pay the recommended civil monetary penalty within thirty (30) days of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check of money order to:

Wells Fargo Bank Attn: State of MD - Board of Pharmacy Lockbox 2051 401 Market Street Philadelphia, PA 19106

NOTE: Please include the case number, <u>24-359</u>, on your check or money order to ensure proper assignment to your case.

Upon the Distributor's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to this matter, and shall be a public document in accordance with the Maryland Public Information Act and posted and reported in accordance with State and federal laws.

If you have any questions concerning the instructions contained in this letter, please contact Trina Leak, Pharm.D., Compliance Director, at 443-635-8318.

Sincerely,

Deena Speights- Napata, M.A.

Executive Director