

Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary

Maryland Board of Pharmacy Kristopher Rusinko, PharmD, Board President Deena Speights-Napata, M.A., Executive Director 4201 Patterson Avenue Baltimore, MD 21215-2299

April 15, 2025

VIA CERTIFIED & REGULAR MAIL RETURN RECEIPT REQUEST ARTICLE# 7019 2280 0000 6569 4485

Aphena Pharma Solutions MD, LLC 7978 Industrial Park Road Easton, Maryland 21601 Attn: Ivan Ordonez, General Manager

RE: Permit No. D05805

Case No. 25-236

Notice of Deficiencies, Imposition of Civil Monetary Penalty, and

Opportunity for Hearing

Dear Permit Holder:

On June 11, 2024, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Aphena Pharma Solutions MD, LLC, (the "Distributor") located in Easton, Maryland. The Board inspector noted that the individuals identified as the Distributor's Designated Representative and Immediate Supervisor were not the same individual identified on the Distributor's application to the Board, and thus had not submitted to a criminal background check as required by Maryland law.

I. FINDINGS AND CONCLUSION

The Board finds that the Distributor failed to submit notification to the Board of the change in its Designated Representative and Immediate Supervisor within 30 days of the change, and thus the Distributor has failed to comply with minimum requirements to have its Designated Representative and Immediate Supervisor submit to a criminal background check to order to obtain a wholesale distributor's permit.

Notice of Deficiencies, Imposition of Civil Monetary Penalty, and Opportunity for Hearing Aphena Pharma Solutions MD, LLC Permit # D05908

Based upon the Distributor's failure to provide notice within 30 days of its change of Designated Representative and Immediate Supervisor and failure to have such personnel submit to a criminal background check, the Board finds that the Distributor is subject to disciplinary action in accordance with the Maryland Pharmacy Act and the regulations adopted thereunder. Health Occ. Art. §§ 12-601; 12-6C-05.1; COMAR 10.34.22.03B and I.

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 infractions above, the Board hereby recommends the imposition of a **civil monetary penalty of \$1,000.00**.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

III. FOLLOW-UP ACTION REQUIRED

Please be advised that the Distributor shall submit immediate notice of its change in Designated Representative and Immediate Supervisor to the Board and shall have its new Designated Representative and Immediate Supervisor submit to a CJIS criminal background check for the Board's review.

IV. OPPORTUNITY FOR HEARING

If the Distributor disputes the findings, conclusions or the recommended 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 Manager, 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

Notice of Deficiencies, Imposition of Civil Monetary Penalty, and Opportunity for Hearing Aphena Pharma Solutions MD, LLC Permit # D05908

summation and argument. Should the Board find the Distributor in violation of the Maryland Pharmacy Act, the Board may reprimand, suspend or revoke the 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 or 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>25-236</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 the Inspection, dated June 11, 2024, and shall be a public document in accordance with the Maryland Public Information Act, Md. Ann. Code, General Provisions Art. § 4-101 *et seq.*, 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 443-685-8318.

Sincerely,

Deena Speights- Napata, M.A.

Executive Director

cc: Linda Bethman, Board Counsel