



NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE AND E-MAIL

March 14, 2025

Mezzion Pharma Co. Ltd
1 Bridge Plaza, Suite 1008
Fort Lee, New Jersey 07024
Attention: Dean Park, M.B.A., Chief Executive Officer
WG Kim, Executive Director

Re: Noncompliance with the Requirements for Submission of Clinical Trial Results Information for “A Phase III Extension Study of Udenafil in Adolescents With Single Ventricle Physiology After Fontan Palliation” (NCT03013751)
FDA Reference Number: CDER-2024-108

Dear Mr. Park and Mr. Kim:

The U.S. Food and Drug Administration (FDA) sent your company a letter dated December 15, 2023, alerting it to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank, operated by the National Library of Medicine, a part of the National Institutes of Health, for the above-referenced clinical trial. Mezzion Pharma Co. Ltd is the “responsible party”¹ for the above-referenced clinical trial, which is an “applicable clinical trial”² that is subject to the requirements in section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date³ of the applicable clinical trial, unless the responsible party has submitted a timely certification of delay, a request for an extension for good cause, or a request for a waiver of the requirements for submission of results information.⁴

¹ See sections 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of “responsible party.”

² See sections 402(j)(1)(A)(i)-(iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)-(iii)) and 42 CFR 11.10 for the definition of “applicable clinical trial.”

³ See 42 CFR 11.10 for the definition of “primary completion date.” See also section 402(j)(1)(A)(v) of the PHS Act (42 U.S.C. 282(j)(1)(A)(v)), which defines “completion date.” As reflected in 42 CFR 11.10, the terms “primary completion date” and “completion date” are synonymous for purposes of 42 CFR part 11.

⁴ See sections 402(j)(3)(E) and (H) of the PHS Act (42 U.S.C. 282(j)(3)(E) and (H)) and 42 CFR part 11 subpart C for results submission requirements.

In our December 15, 2023, letter, we requested that your company review its records for this clinical trial and submit all required results information promptly. We also stated that we intended to further review and assess this clinical trial beginning 30 calendar days after your company received our December 15, 2023, letter, and that we might take regulatory action if we determined that your company was not in compliance at that time. Despite extensive email correspondence between your company, FDA, and/or NLM after Mezzion Pharma Co. Ltd received the December 15, 2023, letter, results information has not been submitted.

FDA has determined that your company failed to submit results information for the applicable clinical trial referenced above, as required under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)) and 42 CFR 11.48.⁵ Moreover, FDA has determined that your company failed to update the responsible party contact information for this clinical trial as required under 42 CFR 11.64(a)(1)(ii)(L).⁶ Pursuant to section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)), FDA is notifying you that your company is not in compliance with FDAAA's information submission requirements, which include the requirements in 42 CFR part 11, and is providing your company with the opportunity to remedy its noncompliance by submitting the required clinical trial information within 30 calendar days after you receive this Notice of Noncompliance (Notice).

Because failure to submit clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(jj)(2)), FDA may initiate an administrative action seeking a civil money penalty against your company. Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. 333(f)(3)(A)), "[a]ny person who violates section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] shall be subject to a civil money penalty of not more than \$10,000 for all violations adjudicated in a single proceeding."⁷

If your company does not submit the required clinical trial information in the manner and format specified at <http://prsinfo.clinicaltrials.gov> or at <https://clinicaltrials.gov/ct2/manage-recs/how-report> within 30 calendar days after receiving this Notice, FDA may also seek additional civil money penalties against your company. Specifically, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] is not corrected within the 30-day period following receipt of a [notice issued] under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil money penalty of not more than \$10,000 for each day of the violation after such period until the violation is corrected."

⁵ We acknowledge that, as recently as December 28, 2023, your company entered results information for NCT03013751 into the National Library of Medicine Protocol Registration and Results System (PRS); however, your company did not complete the process for submitting results information, and the preliminary steps taken by your company do not constitute submission of results information under 42 CFR 11.44(a).

⁶ For applicable clinical trials initiated on or after January 18, 2017, such as the referenced clinical trial, 42 CFR 11.64(a)(1)(ii)(L) requires that responsible party contact information be "updated not later than 30 calendar days after a change in the responsible party or the contact information for the responsible party."

⁷ The civil monetary penalty amounts in this Notice reflect the amounts listed in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461, note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

In addition to civil money penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

If you have any questions about this Notice, you may call Laurie Muldowney, M.D., at (301) 796-1571. Please have the FDA reference number provided at the top of this Notice available when you call. Alternatively, you may e-mail Dr. Muldowney at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

We request that your company submit a written response to FDA within 30 calendar days after you receive this Notice, stating the actions your company has taken in response to this Notice.

Please direct your response to the address below and include the FDA reference number in all correspondence relating to this matter.

Laurie Muldowney, M.D.
Deputy Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5342
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely,



Michael Rogers, M.S.
Associate Commissioner for Inspections and Investigations
Office of Inspections and Investigations
U.S. Food and Drug Administration

cc: Kelly Williams, Director of Global Clinical Operations
Mezzion Pharma Co. Ltd

John Pressor, M.B.A., Chief Business Officer
Mezzion Pharma Co. Ltd