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June 7, 2024

Jessica J. Lee, MD, MMSc
Division Director, Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: NDA 022524 – Zuplenz® (Ondansetron) Oral Soluble Film, 4 mg and 8 mg
SN-0152
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Lee,

Reference is made to New Drug Application (NDA) 022524 Zuplenz® (Ondansetron) Oral Soluble Film approved on July 2, 2010. Reference is also made to a correspondence dated September 29, 2020 (Seq. No. 0030) in which the NDA applicant at the time (Fortovia Therapeutics, Inc.) submitted a correspondence notifying FDA that the product was discontinued from sale and a correspondence dated January 29, 2021 (Seq. No. 0132), in which ownership of this NDA was transferred from Fortovia Therapeutics, Inc. to Aquestive Therapeutics, Inc. (Sponsor) effective January 29, 2021.

Lastly, reference is made to the following recent communications between Aquestive and FDA:

- On April 23, 2024, the agency issued a PREA Non-Compliance Letter to Aquestive. A response to the letter was requested within a 45-day window.
- On April 30, 2024, Aquestive submitted a Request for Voluntary NDA Withdrawal (Seq. 0050).
- On May 8, 2024, FDA issued an Acknowledge Request to Withdraw Approved NDA Letter. This letter indicated that the withdrawal process has been initiated.

In sum, the Zuplenz NDA is in the process of being withdrawn and is pending publication in the Federal Register.

If you have any questions or need further information related to this submission, please contact me by phone at 908-941-1753 or by email at mcioffi@aquestive.com.

Sincerely,

Melina Cioffi, Pharm.D.
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Aquestive Therapeutics
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