Office of Clinical Pharmacology Memo

NDA	NDA 205394/S-0005
EDR location	\\CDSESUB1\evsprod\NDA205394\0043
Submission Type	505 (b)(2) Prior Approval Supplement – Efficacy
Associated IND	110753
Submission Date	04/29/2025
Approved product	Rizafilm (10 mg strength)
Proposed Dosage Form	Oral Soluble film (5 mg strength)
Proposed Dosage Regimen	In pediatric patients 6 years and older: 5 mg in subjects weighing < 40 kg, and 10 mg in patients ≥ 40 kg
Proposed Indication	Acute treatment of migraine with or without aura in adults and pediatric patients 6 years and older
Applicant	Gensco Laboratories, LLC.
OCP Division	Division of Neuropsychiatric Pharmacology (DNP)
OCP Reviewers	Gopichand Gottipati, Ph.D., Poonam Delvadia, Ph.D.

Background

The Applicant, Gensco Laboratories, LLC. dba Gensco-Pharma (Gensco) is submitting the current prior efficacy supplement for NDA 205394 to add a new pediatric strength of 5mg RizaFilm (rizatriptan) oral film. Rizafilm was approved in April 2023 for the acute treatment of migraine with or without aura in adults and pediatric patients between 12 to 17 years of age weighing 40 kg or more (See Clinical Pharmacology Review in DARRTS, dated 03/15/2019). At the time of the approval, a 5 mg dose strength of RizaFilm was not available, and therefore, a dose adjustment to 5 mg for pediatric patients aged 6 to 17 years that are <40 kg and adult or pediatric patients ≥ 40 kg taking propranolol concomitantly was not possible. A post-marketing requirement (PMR) 4434-1 was issued to develop age-appropriate dose strength of RizaFilm for administration to pediatric patients 6 to 11 years of age. Subsequently, the Agency provided feedback on the CMC and biowaiver request related questions in a Type C meeting in July 2023 (See Meeting minutes dated 07/19/2023 in DARRTS).

Summary of Clinical Pharmacology Recommendations

The Office of Clinical Pharmacology (OCP) review team defers the determination regarding the biowaiver for 5 mg dosage strength to the Biopharmaceutics team, Office of Pharmaceutical Quality (OPQ). OCP reviewed the information provided in the applicant's response (dated 07/01/2025) to the information request (Dated 06/23/2025) regarding the linearity of rizatriptan PK in the 5 – 10 mg range and agrees with the applicant.

If the biowaiver for 5 mg dosage strength was deemed acceptable, OCP team supports the approval of 5 mg dosage strength in pediatric patients aged 6 to 17 years that are <40 kg and adult or pediatric patients ≥ 40 kg taking propranolol concomitantly and revisions in sections:

- 2.2: Addition of dosing in pediatric subjects 6 to 17 years that are < 40 kg,
- 2.4 and 7.1: Addition of section 2.4 on dosage adjustment for adult and pediatric subjects ≥ 40 kg taking propranolol and appropriate edits to reflect the recommendation in section 7.1,
- 4: Revision of contraindication to pediatric subjects < 40 kg taking propranolol.

In addition, OCP review team recommends minor edits in sections 8 and 12.3, namely removal of lbs, since the weight in kg appropriately addresses the dosage recommendations.

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/s/

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