Summary Review

Date	February 22, 2026
From	Heather Fitter, M.D. Laura Jawidzik, MD
Subject	Summary Review
NDA #	205934/S-05
Applicant	Gensco Laboratories, LLC
Date of Submission	April 29, 2025
PDUFA Goal Date	February 28, 2026
Proprietary Name / Established (USAN) names	RizaFilm/Rizatriptan oral film
Dosage forms / Strength	Oral soluble film (5 mg)
Applicant Proposed Dosing Regimen	6 years and older: 5 mg in patients weighing less than 40 kg and 10 mg in patients weighing equal to or greater than 40 kg.
Proposed Indication	Acute treatment of migraine with or without aura in adults and pediatric patients 6 years and older
Recommendation on Regulatory Action:	Approval

1. Introduction/Background

The Applicant, Gensco Laboratories Limited, submitted a supplemental efficacy application for NDA 205394 (associated IND 110753) to add a new pediatric strength of 5 mg RizaFilm oral film to address the Pediatric Research Equity Act (PREA) post marketing requirement (PMR) issued during the original approval of NDA 205394 (April 14, 2023). The original approval of RizaFilm was based on a 505(b)(2) regulatory pathway relying on the determination by FDA of safety and efficacy of the listed drug (LD), Maxalt-MLT (NDA 020865). Although the listed drug labeling allows for dosing down to age 6 when using a 5 mg formulation, the sponsor of Rizafilm did not submit chemistry, manufacturing and controls (CMC) information for a 5 mg formulation with the application mentioned above; therefore, the indication could not be extended down to age 6. At the time of approval, a PREA PMR (4431-1) was issued to require that the Applicant develop an age-appropriate dose strength of RizaFilm for administration to pediatric patients 6 through 11 years of age.

In addition, because a 5 mg dose was not available when RizaFilm was originally approved, no dose adjustment was available for subjects taking concomitant propranolol and therefore the use of propranolol with RizaFilm was contraindicated.

The current application includes information from one batch of the 5 mg strength (batch 24AL005P1), dissolution testing on the new strength and a biowaiver request for the new strength.

2. Office of Product Quality

Drug Substance
N/A

Drug Product
Dr. Fengting Laing was the primary drug product quality reviewer for this application and Dr. Richard Matsuoka was the secondary reviewer. Dr. Laing states that RizaFilm oral film 10 mg was approved April 2023, through a 505(b)(2) regulatory pathway by establishing bioequivalence to the reference products Maxalt-MLT 10 mg orally disintegrating tablets and Maxalt-lingua 10 mg oro-dispersible tablets, for the acute treatment of migraine with or without aura in adults and pediatric patients 12 to 17 years of age weighing 40 kg or more.

To support the proposed addition of the new pediatric strength, the Applicant manufactured and packaged one registration batch (batch # 24AL005P1, (b) (4) units) of RizaFilm (rizatriptan) oral film 5 mg. All relevant CMC sections were amended to add information for the 5 mg strength drug product and are submitted with this application.

The registration batch size ((b) (4) kg) and composition for both the 5 mg strength and 10 mg strength drug products are identical to those proposed for commercial manufacture, with no changes proposed to the formulation. Manufacturing of rizatriptan oral film 5 mg includes a

(b) (4)

The proposed drug product with 5 mg strength is a white to off-white to yellowish rectangular oral film containing 5 mg of rizatriptan (7.265 mg of rizatriptan benzoate). Test results of (b) (4) passed in process specifications. All risks are reduced to medium or low at each stage during the manufacturing procedure. The process (b) (4) met the established control limits (b) (4) as per the executed batch records for the registration batch of the 5 mg strength drug product.

The currently approved analytical procedures and validation of the analytical procedures for rizatriptan oral film 10 mg were updated to include the proposed 5 mg strength. Batch analysis data (certificate of analysis) for the registration batch of rizatriptan oral film 5 mg (batch # 24AL005P1) met the proposed specifications.

Both 5 mg and 10 mg oral films are packaged using the same packaging material, and the pouch sizes for each strength are identical. Six (6)-month stability data at accelerated and long-term conditions for the 5 mg registration batch are well within the stability specification limits

for all testing parameters, including impurity [redacted] (b) (4). The drug product OPQ team recommends approval for this supplement.

Biopharmaceutics
Dr. Hansong Chen was the primary biopharmaceutics quality reviewer and Dr. Ta-Chen Wu was the secondary reviewer. The Applicant manufactured one batch of the 5 mg strength product. Dissolution testing on the new strength was performed using the FDA approved dissolution method for RizaFilm oral dissolving film. The Applicant also submitted a biowaiver request for the new strength.

Dr. Chen states that individual dissolution data of 5 mg strength in the approved medium indicate that batch 24AL005P1 meets the approved dissolution acceptance criterion.

Dr. Chen concludes that a biowaiver can be granted for the proposed new 5 mg strength for the following reasons: (1) The formulation of lower strength is proportionally similar in composition to the approved higher strength (i.e., 10 mg); (2) Both strengths have the same release mechanism and manufacturing process; (3) The higher strength and lower strength have comparable dissolution profiles; and (4) There is evidence of pharmacokinetic (PK) linearity over the proposed dose range. The Biopharmaceutical team recommends approval for this supplement.

Office of Pharmaceutical Manufacturing Assessment (OPMA)
Dr. Mina Chang conducted the facility inspection and recommended approval of this supplement.

3. Nonclinical Pharmacology/Toxicology

N/A

4. Office of Clinical Pharmacology

Dr. Gopichand Gottipati was the primary reviewer from the Office of Clinical Pharmacology (OCP) and Dr. Poonam Delvadia was the team leader.

Dr. Gottipati states that the Applicant submitted the current prior efficacy supplement for NDA 205394 to add a new pediatric strength of 5mg RizaFilm (rizatriptan) oral film. As stated above, 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. A clinical pharmacology review was entered in DARRTS on March 15, 2019, for the original RizaFilm application which included only the dose strength of 10 mg. Because a 5 mg dose strength of RizaFilm was not available, 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. Because this application triggered PREA, 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. The Division also provided feedback in a Type C meeting on July 19, 2023, regarding CMC and biowaiver request related questions.

The Office of Clinical Pharmacology (OCP) review team deferred 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 July 1, 2025) to the information request (dated June 23, 2025) regarding the linearity of rizatriptan PK in the 5 – 10 mg range and agreed with the Applicant that linearity was demonstrated. Because OPQ concluded that a 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 proposes revisions in labeling in the following 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 patients taking propranolol and appropriate edits to reflect the recommendation in section 7.1,
- 4: Modification of contraindication in patients taking propranolol to be restricted to pediatric patients who weigh less than 40 kg.

5. Clinical/Efficacy

No additional efficacy or safety studies were done since efficacy in the pediatric population is relied upon based on the previous findings of efficacy in this population for the LD.

6. Safety

No additional efficacy or safety studies were done since safety in the pediatric population is relied upon based on the previous findings of safety in this population for the LD.

7. Division of Medication Error Prevention and Analysis

Dr. Beverly Weitzman was the Division of Medication Error Prevention and Analysis (DMEPA) primary reviewer and Dr. Stephanie DeGraw conducted the secondary review.

The Applicant submitted revised container labels and carton labeling for the proposed 5 mg strength and the approved 10 mg strength of Rizafilm. DMEPA reviewed the revised container labels and carton labeling for Rizafilm to determine if they are acceptable from a medication error perspective. DMEPA states that the Applicant implemented all of FDA's recommendations for the proposed 5 mg strength container label and carton labeling. DMEPA concludes that the container label and carton labeling for both the 5 mg and 10 mg strength of RizaFilm are acceptable from a medication error perspective.

8. Advisory Committee Meeting

N/A

9. Pediatrics

The information provided in this application fulfills PREA PMR 4431-1.

10. Labeling

Labeling was agreed upon with the Applicant.

11. Recommendations/Risk Benefit Assessment

An Approval action will be taken for this NDA for the addition of the 5 mg dose strength for RizaFilm. This additional dose strength will allow for dosing to pediatric patients down to age 6 for RizaFilm. Therefore, the information submitted in this application allows for fulfillment of the PREA PMR imposed with the original NDA submission for RizaFilm. In addition, this dose strength allows for a dose adjustment of RizaFilm in subjects who weigh 40 kg or more and are taking concomitant propranolol. Labeling will still include a contraindication for pediatric subjects that weigh less than 40 kg because dosing to individuals that weigh less than 40 kg would require a lower dose option, which is not available. Efficacy and safety for RizaFilm in the pediatric population down to age 6 is supported based on the demonstration of bioequivalence of RizaFilm to the LD, Maxalt-MLT, reviewed in the original RizaFilm application.

The Office of Product Quality and the Office of Clinical Pharmacology determined that the information submitted for dissolution and for a biowaiver for the 5 mg dose strength is acceptable.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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02/26/2026 12:59:22 PM

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02/26/2026 01:04:33 PM