NDA 205394/S-007

SUPPLEMENT APPROVAL

Gensco Laboratories LLC
c/o Foley and Lardner LLP
Attention: David Rosen BS, Pharm JD
3000 K Street N.W., Suite 600
Washington, DC 20007

Dear David Rosen:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 31, 2025, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RizaFilm (rizatriptan) oral film.

This “Changes Being Effected” supplemental new drug application provides for the following:

1) The removal of the language "Store pouches in carton" and "Dispense in this sealed carton" from the outer carton (secondary container) to align with the practical use of the product dispensing.
2) The addition of "Made in Canada" to the labeling to reflect the manufacturing origin.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 205394/S-007.**” Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

Vilayat Sayeed, Ph.D.
Director
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

Vilayat Sayeed

Digitally signed by Vilayat Sayeed
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