



NDA 217171/S-003

SUPPLEMENT APPROVAL

Apellis Pharmaceuticals, Inc
Attention: Hanaa Shahin
Director, Regulatory Affairs
100 5th Avenue
3rd Floor
Waltham, MA 02451

Dear Hanaa Shahin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 27, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SYFOVRE (pegcetacoplan injection).

This Prior Approval supplemental new drug application provides for introduction of a co-pack configuration and updates to the US Prescribing Information (PI).

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format,

that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 217171/S-003.**” Approval of this submission by FDA is not required before the labeling is used.

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 Emma Gimose, Regulatory Business Process Manager, at Emma.Gimose@fda.hhs.gov or (240) 402 - 1681.

Sincerely,

{See appended electronic signature page}

Nina Ni, PhD
Supervisor
Division of Product Quality Assessment VII
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Carton and Container Labeling

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SYFOVRE safely and effectively. See full prescribing information for SYFOVRE.

SYFOVRE® (pegcetacoplan injection), for intravitreal use
Initial U.S. Approval: 2021

RECENT MAJOR CHANGES

Dosage and Administration, Preparation for Administration (2.3) MM/2025
Contraindications, Hypersensitivity (4.3) 12/2024

INDICATIONS AND USAGE

SYFOVRE is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). (1)

DOSAGE AND ADMINISTRATION

The recommended dose for SYFOVRE is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days. (2.2)

DOSAGE FORMS AND STRENGTHS

Injection: 150 mg/mL in a single-dose vial. (3)

CONTRAINDICATIONS

- Ocular or Periocular Infections (4.1)
- Active Intraocular Inflammation (4.2)
- Hypersensitivity (4.3)

WARNINGS AND PRECAUTIONS

- Endophthalmitis and Retinal Detachments (5.1)
- Retinal Vasculitis and/or Retinal Vascular Occlusion (5.2)
- Neovascular AMD (5.3)
- Intraocular inflammation (5.4)
- Increased Intraocular Pressure (5.5)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥5%) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, and conjunctival hemorrhage. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Apellis Pharmaceuticals, Inc. at 1-833-866-3346 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: MM/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

- 2.1 General Dosing Information
- 2.2 Recommended Dosage
- 2.3 Preparation for Administration
- 2.4 Injection Procedure

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

- 4.1 Ocular or Periocular Infections
- 4.2 Active Intraocular Inflammation
- 4.3 Hypersensitivity

5 WARNINGS AND PRECAUTIONS

- 5.1 Endophthalmitis and Retinal Detachments
- 5.2 Retinal Vasculitis and/or Retinal Vascular Occlusion
- 5.3 Neovascular AMD
- 5.4 Intraocular Inflammation
- 5.5 Increased Intraocular Pressure

6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience
- 6.2 Postmarketing Experience

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Lactation
- 8.3 Females and Males of Reproductive Potential
- 8.4 Pediatric Use
- 8.5 Geriatric Use

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics
- 12.6 Immunogenicity

13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

- 16.1 How Supplied
- 16.2 Storage and Handling

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.



Nina
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Digitally signed by Nina Ni

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