BLA 761486

BLA ACCELERATED APPROVAL

Vera Therapeutics, Inc.
Attention: Erin Collins, MS, RAC
Senior Director, Clinical Regulatory Affairs
2000 Sierra Point Parkway
Suite 1200
Brisbane, CA 94005

Dear Erin Collins:

Please refer to your biologics license application (BLA) dated and received November 7, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Trutakna (atacicept-vymj) injection.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2386 to Vera Therapeutics, Inc., South San Francisco, California, under the provisions of section 351(a) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product Trutakna (atacicept-vymj). Trutakna is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture atacicept-vymj drug substance at (b) (4) The (b) (4) final formulated prefilled syringe (PFS) drug product will be manufactured and filled at (b) (4) The filled drug product will be assembled with the autoinjector device at (b) (4) The final drug product is labeled and packaged at (b) (4) (b) (4) You may label your product with the proprietary name Trutakna and will market it as a 150 mg/mL injection in a single-dose pre-filled autoinjector.

DATING PERIOD

The dating period for Trutakna shall be 24 months from the date of manufacture when stored at 2°C to 8°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be (b) (4) months from the date of manufacture when stored at (b) (4)

We have approved the stability protocol(s) in your license application for the purpose of extending the expiration dating period of your drug product under 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Trutakna to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Trutakna, or in the manufacturing facilities, will require the submission of information to your biologics license application for our review and written approval, consistent with 21 CFR 601.12.

APPROVAL AND LABELING

We have completed our review of this application, as amended. It is approved under accelerated approval pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) and 21 CFR 601.41, effective on the date of this letter, for use as recommended in the enclosed agreed-upon approved labeling.

Marketing of this drug product and related activities must adhere to the substance and procedures of the accelerated approval statutory provisions and regulations.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use). Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to 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 "**Final Printed Carton and Container Labeling for approved BLA 761486**." Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for Trutakna was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues that were unexpected for a biologic of this class and there were no controversial issues that would benefit from advisory committee discussion.

ACCELERATED APPROVAL REQUIREMENTS

Pursuant to section 506(c) of the FDCA and 21 CFR 601.41, you are required to conduct an adequate and well-controlled clinical trial intended to verify and describe clinical benefit. You are required to conduct this clinical trial with due diligence. If the required postmarketing clinical trial fails to verify clinical benefit or is not conducted with due diligence, including with respect to the conditions set forth below, we may withdraw this approval. We remind you of your postmarketing requirement specified in your submission dated June 22, 2026. This requirement is listed below.

4970-1 Conduct a randomized, double-blind, placebo-controlled trial to describe and verify the clinical benefit of Trutakna for the treatment of primary IgAN. The trial should be adequately powered and of sufficient duration to detect a treatment effect on the endpoint that will be used to describe and verify the clinical benefit.

The timetable you submitted on June 22, 2026, states that you will conduct this study/trial according to the following schedule:

Final Protocol Submission:	Completed
Trial Completion:	03/2027
Final Report Submission:	07/2027

Submit clinical protocols to your IND 122043 for this product. FDA considers the term final to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.

You must submit reports of the progress of each clinical trial required under section 506(c) (listed above) to this BLA 180 days after the date of approval of this BLA and approximately every 180 days thereafter (see section 506B(a)(2) of the FDCA) (hereinafter "180-day reports").

You are required to submit two 180-day reports per year for each open study or clinical trial required under 506(c). The initial report will be a standalone submission and the subsequent report will be combined with your application's annual status report (ASR) required under section 506B(a)(1) of the FDCA and 21 CFR 601.70. The standalone 180-day report will be due 180 days after the date of approval (with a 60-day grace period). Submit the subsequent 180-day report with your application's ASR. Submit both of these 180-day reports each year until the final report for the corresponding study or clinical trial is submitted.[3]

Your 180-day reports must include the information listed in 21 CFR 601.70(b). FDA recommends that you use FORM FDA 3989, *PMR/PMC Annual Status Report for Drugs and Biologics,* to submit your 180-day reports.[4]

The 180-day reports must be clearly designated "**BLA 761486 180-Day AA PMR Progress Report**."

FDA will consider the submission of your application's ASR under section 506B(a)(1) and 21 CFR 601.70, in addition to the submission of reports 180 days after the date of approval each year (subject to a 60-day grace period), to satisfy the periodic reporting requirement under section 506B(a)(2).

Submit final reports to this BLA as a supplemental application. For administrative purposes, the cover page of all submissions relating to this postmarketing requirement must be clearly designated "**Subpart E Postmarketing Requirement(s)**."

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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

[3] You are required to submit information related to your confirmatory trial as part of your annual reporting requirement under section 506B(a)(1) until the FDA notifies you, in writing, that the Agency concurs that the study requirement has been fulfilled or that the study either is no longer feasible or would no longer provide useful information.

[4] FORM FDA 3989, along with instructions for completing this form, is available on the FDA Forms web page at https://www.fda.gov/about-fda/reports-manuals-forms/forms .

the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirement for ages from birth to less than 2 years as necessary studies are impossible or highly impracticable because IgAN is extremely rare in this age group.

We are deferring submission of your pediatric study for ages 2 to 17 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required under section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 601.28 and section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

4970-2 Conduct a pharmacodynamic, pharmacokinetic, safety and tolerability study of Trutakna in pediatric patients 2 years to 17 years of age with primary IgAN. The pharmacodynamic assessment should be based on effects on proteinuria.

Final Protocol Submission: Completed
Study Completion: 07/2031
Final Report Submission: 12/2031

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial. See guidance for industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act.*

Submit the protocol to your IND 122043, with a cross-reference letter to this BLA. Reports of this required pediatric postmarketing study must be submitted as a BLA or as a supplement to your approved BLA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission **"SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS"** in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify unexpected serious risks of the potential fetal exposure to Trutakna with unknown safety implications for human pregnancy outcomes, and the potential transfer of Trutakna into human milk with unknown effects on the breastfed infant.

Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following studies:

4970-3 Conduct a worldwide descriptive study that collects prospective and retrospective data in women exposed to Trutakna during pregnancy to assess risk of pregnancy and maternal complications, and adverse effects on the developing fetus, neonate, and infant. Assess infant outcomes through at least the first year of life. The minimum number of patients will be specified in the protocol.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	01/2027
Final Protocol Submission:	07/2027
Study/Trial Completion:	07/2037
Final Report Submission:	01/2038

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[5]

4970-4 Perform a lactation study in lactating women who have received Trutakna to measure concentrations of atacicept-vymj and its major metabolites in breast milk using a validated assay. Assess the effects on the breastfed infant, if available, based on study population.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	01/2027
Final Protocol Submission:	07/2027
Study Completion:	07/2029
Final Report Submission:	01/2030

[5] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Submit clinical protocol(s) to your IND 122043 with a cross-reference letter to this BLA. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your BLA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate: **REQUIRED POSTMARKETING PROTOCOL UNDER 505(o), REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o), REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o).**

Submission of the protocol(s) for required postmarketing observational studies to your IND is for purposes of administrative tracking only. These studies do not constitute clinical investigations pursuant to 21 CFR 312.3(b) and therefore are not subject to the IND requirements under 21 CFR part 312.

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B(a)(1) of the FDCA, as well as 21 CFR 601.70 requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B(a)(1) and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 601.70. We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4970-5	Develop and validate a sensitive assay(s) for accurate detection of neutralizing antibodies (NAb) to atacicept-vymj in the presence of drug levels that are expected in the serum or plasma at the time of patient sampling. This assay will be used to assess NAb activity of patient samples that tested positive for anti-drug antibodies (ADA). The NAb assay procedures and supportive method validation data will be submitted in the final report to the BLA.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 07/2028

4970-6 Conduct a study to analyze banked immunogenicity serum samples from the pivotal clinical trials including Study VT-001-0050 (ORIGIN and ORIGIN 3) and the pediatric study under PMR 4970-2 to characterize the neutralizing activity of ADA using a validated NAb assay. Evaluate the impact of NAb on atacicept-vymj pharmacokinetics and efficacy in subjects with immunoglobulin A nephropathy based on the data generated with the NAb assay.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 12/2031

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4970-7 Validate and implement the surface plasmon resonance (SPR) assay to control the binding activity of atacicept-vymj to APRIL for drug substance and drug product lot release and stability testing. Submit the analytical procedure description, validation report, proposed acceptance criterion, and data used to set the proposed acceptance criterion for the APRIL binding assay to the BLA in a post-approval supplement.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 03/2027

4970-8 Optimize the SE-HPLC method for protein concentration determination to reduce variability associated with (b) (4). Submit the updated analytical procedure description and data to support the suitability of the optimized SE-HPLC method for Trutakna drug product release and stability testing in a post-approval supplement.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 01/2027

4970-9 Analyze the potency of atacicept-vymj drug substance and drug product clinical batch retains using the newly established working reference standard (b) (4) Use these empirical results to re-

evaluate and, if appropriate, revise the mathematically derived release and stability acceptance criteria for biological activity. Submit the analytical data, the re-evaluation, the revised acceptance criteria (if needed) and supporting scientific justification to the BLA.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 01/2027

4970-10 Develop, validate, and implement a suitable test for direct control of CHO-derived (b) (4) host cell protein. Submit the analytical procedure description, method validation report, proposed acceptance criterion, and justification for the proposed acceptance criterion to the BLA in a post-approval supplement.

The timetable you submitted on June 22, 2026, states that you will conduct this study according to the following schedule:

Final Report Submission: 03/2027

PROMOTIONAL MATERIALS

Under 21 CFR 601.45, you are required to submit, during the application pre-approval review period, all promotional materials, including promotional labeling and advertisements, that you intend to use in the first 120 days following marketing approval (i.e., your launch campaign). If you have not already met this requirement, you must immediately contact the Office of Prescription Drug Promotion (OPDP) at (301) 796-1200. Please ask to speak to a regulatory project manager or the appropriate reviewer to discuss this issue.

As further required by 21 CFR 601.45, submit all promotional materials that you intend to use after the 120 days following marketing approval (i.e., your post-launch materials) at least 30 days before the intended time of initial dissemination of labeling or initial publication of the advertisement. We ask that each submission include a detailed cover letter together with three copies each of the promotional materials, annotated references, and approved Prescribing Information, Medication Guide, and Patient Package Insert (as applicable).

For information about submitting promotional materials, see guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (21 CFR 600.80).

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements for licensed biological products (21 CFR 600.81).

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

POST APPROVAL FEEDBACK MEETING

New molecular entities and new biologics qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, please contact Maryam Changi, Regulatory Project Manager, at maryam.changi@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Hylton V. Joffe, MD, MMSc
Director
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

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/

HYLTON V JOFFE
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