Our STN: BL 125702/0

BLA APPROVAL
July 29, 2026

Vascular Solutions, LLC (a subsidiary of Teleflex)
Attention: Erika Beck
6420 Sycamore Lane North
Maple Grove, MN 55369

Dear Erika Beck:

We acknowledge receipt of your amendment dated September 29, 2025, which constituted a complete response to our September 2, 2021, action letter.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2135 to Vascular Solutions, LLC (a subsidiary of Teleflex), Maple Grove, Minnesota, under the provisions of section 351(a) of the PHS 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 Freeze Dried Plasma, which is indicated for transfusion in adults when plasma is required and other plasma products are not available. Indications include:

1. Management of preoperative or bleeding patients who require replacement of multiple plasma coagulation factors [e.g., liver disease, disseminated intravascular coagulation (DIC)].

2. Patients undergoing massive transfusion who have clinically significant coagulation deficiencies.

3. Patients taking warfarin who are bleeding or need to undergo an invasive procedure before vitamin K could reverse the warfarin effect or who need only transient reversal of warfarin effect.

The review of this product was associated with the following National Clinical Trial (NCT) number: NCT02930226

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Freeze Dried Plasma from Fresh Frozen Plasma obtained from U.S. licensed blood establishments, with your lyophilization bag container as an aseptic manufacturing system, in accordance with your approved standard operating procedures at your facility located at Vascular Solutions, LLC (a subsidiary of Teleflex), 6420 Sycamore Lane North, Maple Grove, Minnesota, 3002827704. You must label your product with the proper name, Freeze Dried Plasma that we have approved, and market it as approved in your license application.

DATING PERIOD

The dating period for Freeze Dried Plasma shall be 12 months from the date of manufacture when stored at 2–25°C (36–77°F). The date of manufacture shall be defined as the date of final labeling. The product must be infused within 4 hours of reconstitution.

ADVISORY COMMITTEE

We did not refer your application to the Blood Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 606.171. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, and 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 the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations :

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in manufacturing including but not limited to the processing, lyophilization, testing, packaging, labeling or storage of Freeze Dried Plasma, or any changes in the manufacturing facilities.

LABELING

We hereby approve your final container labels submitted under amendment 73, dated March 13, 2026, and amendment 81, dated May 14, 2026, and the Circular of Information submitted under amendment 92, dated July 27, 2026.

This is a reminder that as of September 24, 2014, device constituents of combination products may be subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device constituent label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18 and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device constituent, and the device identifiers that have been discontinued for the subject device constituent as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website at http://www.fda.gov/udi.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
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You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must maintain records of adverse reactions in accordance with 21 CFR 606.170(a).

Also, in accordance with 21 CFR 606.170(b), you must notify the Director, Office of Compliance and Biologics Quality, CBER, of transfusion related fatalities by telephone, facsimile, express mail, or secure email as soon as possible. A written report of the investigation must be submitted to the Director, Office of Compliance and Biologics Quality, CBER, by mail, facsimile, or electronically transmitted mail within 7 days after the fatality. The mailing address for fatality reports is:

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For information on the postmarketing safety reporting requirements for combination products as described in 21 CFR 4, Subpart B, and the dates by which combination product applicants must comply with these requirements, please refer to the Postmarketing Safety Reporting for Combination Products webpage available at Postmarketing Safety Reporting for Combination Products | FDA.

PEDIATRIC REQUIREMENTS

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric study protocol until 2031.

The pediatric study should be delayed until additional safety or effectiveness data have been collected from the adult Phase 4 Postmarketing Requirement study.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. This required study is listed below:

1. Deferred pediatric study under PREA is indicated for transfusion when plasma is required and other conventional plasma products are not available in pediatric patients ages birth to less than 17 years.

   Final Protocol Submission: December 31, 2031

   Study Completion Date: December 31, 2035

   Final Report Submission: December 31, 2036

Submit the protocol to your IND 17154, with a cross-reference letter to this BLA, STN BL 125702 explaining that this protocol was submitted to the IND.

Submit final study reports to this BLA STN BL 125702. In order for your PREA PMR to be considered fulfilled, you must submit and receive approval of either an efficacy or a labeling supplement. For administrative purposes, all submissions related to this required pediatric postmarketing study must be clearly designated as:

- **Required Pediatric Assessment**

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (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 (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that adverse event reporting alone will not be sufficient to identify the potential serious risk of thrombotic/thromboembolic events (TTE).

Additionally, we have determined that only a clinical trial rather than a nonclinical or observational study will be sufficient to identify an unexpected serious risk of thrombotic/thromboembolic events.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following clinical trial:

2. A Phase 4, Cluster-Randomized Crossover, Prospective, Multi-Center Trial Evaluating the Safety of Freeze-Dried Plasma and Conventional Plasma Products in Adult Patients.

We acknowledge the timetable you submitted on July 1, 2026, which states that you will conduct this clinical trial according to the following schedule:

Protocol Submission: September 30, 2026

Trial Completion Date: May 31, 2031

Final Report Submission: December 31, 2031

Please submit the protocol to your IND 17154, with a cross-reference letter to this BLA, STN BL 125702, explaining that this protocol was submitted to the IND. Please refer to the sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA, STN BL 125702. For administrative purposes, all submissions related to this postmarketing study required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

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. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,

- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

We will consider the submission of your annual report under section 506B of the FDCA 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 section 505(o) and 21 CFR 601.70. We remind you that to comply with section 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 periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POST APPROVAL FEEDBACK MEETING

New biological products 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, please contact the Regulatory Health Project Manager for this application.

Sincerely,

Anne Eder, MD, PhD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research