Our STN: BL 125251/454

SUPPLEMENT APPROVAL
PMR/PMC FULFILLED
July 2, 2026

OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.
Attention: Sergio Alegre
Octapharma USA, Inc.
117 West Century Road
Paramus, NJ 07652

Dear Mr. Alegre:

We have approved your request received September 02, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for von Willebrand Factor/Coagulation Factor VIII Complex (Human) [WILATE] to fulfill the postmarketing requirement (PMR) #1 under STN 125251/382 by submitting final data from clinical study WIL-33 as well as the required Pediatric Assessment. Based on the provided final data from clinical study WIL-33, this approval action also extends the currently approved indication of routine prophylaxis to reduce the frequency of bleeding episodes in Von Willebrand Disease (VWD) to pediatric patients less than 6 years of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT04953884.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling: Package Insert and Instructions for Use, submitted under amendment 17, dated June 25, 2026.

WAIVER OF HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via 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 Package Insert and Instructions for Use submitted on June 25, 2026. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125251 at the time of use and include implementation information on Form FDA 356h.

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
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement PMR #1 identified in the December 1, 2023, approval letter for BLA STN BL 125251/382 for von Willebrand Factor/Coagulation Factor VIII Complex (Human) [WILATE]. The requirement addressed in this submission is as follows:

PMR #1: Deferred pediatric study under PREA for the treatment of routine prophylaxis in pediatric patients with VWD ages 2 to less than 6 years of age.

Final Protocol Submission: February 2021

Study Completion Date: May 2024

Final Report Submission: (Revised Schedule) September 30, 2025

This completes all of your PMR(s) and PMC(s). As such, your **Annual Status Report of Postmarketing Requirements/Commitments** is no longer required until such time a new Requirement or Commitment subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act is issued.

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 note that you have fulfilled the pediatric study requirement for all ages for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Bindu George, MD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research