



Our STN: BL 125251/419

**SUPPLEMENT APPROVAL**

November 8, 2024

OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.

Attention: Sergio Alegre  
Octapharma USA Inc.  
117 West Century Road  
Paramus, NJ 07652

Dear Sergio Alegre:

We have approved your request received July 10, 2024, 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 1) replace the transfer device Mix2Vial with Nextaro, 2) add (b) (4)

(Water for injection with 0.1% Polysorbate 80) for drug product reconstitution, 3) add (b) (4) as an additional manufacturer of the Solvent (Water for injection with 0.1% Polysorbate 80) for drug product reconstitution, 3) add (b) (4) as an additional site for Solvent testing, and 4) change the size of the folding carton.

## **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 submitted under amendment 7, dated October 15, 2024; Patient Package Insert submitted under amendment 7, dated October 15, 2024; Instructions for Use submitted under amendment 7, dated October 15, 2024; and the draft carton and container labels submitted under amendment 0, dated July 10, 2024.

## **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, Patient Package Insert, and Instructions for Use submitted on October 15, 2024. 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.

## **CARTON AND CONTAINER LABELS**

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on July 10, 2024, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>.

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.

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

Sincerely,

Zuben Sauna, PhD  
Director  
Division of Hemostasis  
Office of Plasma Protein Therapeutics  
Office of Therapeutic Products  
Center for Biologics Evaluation and Research