



Our STN: BL 101447/6157

**SUPPLEMENT APPROVAL**

March 27, 2024

Takeda Pharmaceuticals U.S.A., Inc.  
Attention: Pooja Bhat  
650 E Kendall Street  
Cambridge, MA 02142

Dear Pooja Bhat:

We have approved your request received September 26, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Anti-Inhibitor Coagulant Complex to make labeling changes for regular volume [50 U/mL concentration] and higher infusion rate [up to 10 U/kg/min] in both age groups, adult, and pediatric patients.

## **LABELING**

We hereby approve the draft content of labeling Package Insert submitted under amendment 5004, dated March 6, 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 submitted on March 6, 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.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 101447 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 change approved today.

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

Sincerely,

Lola Fashoyin-Aje, MD, MPH  
Acting Director  
Division of Clinical Evaluation Hematology  
Office of Clinical Evaluation  
Office of Therapeutic Products  
Center for Biologics Evaluation and Research