Our STN: BL 101447/6129

SUPPLEMENT APPROVAL
June 9, 2023

Takeda Pharmaceuticals USA, Inc.
Attention: Intan Emzita, MSc
650 E Kendall Street
Cambridge, MA 02142

Dear Intan Emzita:

We have approved your request received December 9, 2022, to supplement your Biologics License Application (BLA) submitted under section 351 (a) of the Public Health Service Act for FEIBA® (anti-inhibitor coagulant complex) to increase the infusion rate in patients of all ages and to reduce the volume of Sterile Water for Injection (sWFI) used for reconstitution in adult patients over the age of 18 years. To reflect these changes, FEIBA ® Prescribing Information has been updated in Section 2 DOSAGE AND ADMINISTRATION (2.1 Dose, 2.2 Preparation and Reconstitution, 2.3 Administration), Section 5 WARNINGS AND PRECAUTIONS (5.3 Transmission of Infectious Agents), Section 6 ADVERSE REACTIONS (6.2 Postmarketing Experience), Section 11 DESCRIPTION, Section 14 CLINICAL STUDIES (14.2 Routine Prophylaxis), Section 16 HOW SUPPLIED/STORAGE AND HANDLING, and Section 17 PATIENT COUNSELING INFORMATION.

LABELING
We hereby approve the draft content of labeling Package Insert submitted under amendment 5001, dated June 8, 2023, and the draft carton and container labels submitted under amendment 6129, dated December 9, 2022.

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 June 8, 2023. 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 December 9, 2022, 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 a 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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

Sincerely,

Celia Witten, MD, PhD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research