Our STN: BL 125444/793

SUPPLEMENT APPROVAL
October 29, 2020

Bioverativ Therapeutics Inc.
Attention: Valeria Winslow, PhD
Global Regulatory Affairs
225 Second Avenue
Waltham, MA 02451

Dear Dr. Winslow:

This letter supersedes the letter dated October 26, 2020, to include the correct approved prescribing information label date and amendment.

We have approved your request submitted and received on April 27, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Alprolix (Coagulation Factor IX (Recombinant), Fc Fusion Protein), to revise the US Prescribing Information (USPI) to include data from Study 998HB303 titled: *An Open-Label, Multicenter Evaluation of the Safety and Efficacy of Recombinant Coagulation Factor IX Fc Fusion Protein (rFIXFc; BIIB029) in the Prevention and Treatment of Bleeding in Previously Untreated Patients with Severe Hemophilia B*.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT02234310.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 4 dated October 28, 2020.

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. 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.

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.

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.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

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

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research