Our STN: BL 125661/982

SUPPLEMENT APPROVAL
December 2, 2024

Bayer HealthCare LLC
Attention: Sangeeta Patel, MBA, BSC
100 Bayer Blvd.
P.O. Box 915
Whippany, NJ 07981

Dear Sangeeta Patel:

We have approved your request received August 2, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Antihemophilic Factor (Recombinant), PEGylated-aucl [JIVI], to introduce a new dosage strength of 4000 IU for JIVI at the approved manufacturing site in (b) (4)

LABELING

We hereby approve the draft content of labeling (Package Insert) submitted under amendment 0, dated August 2, 2024, and the draft carton and container labels submitted under amendment 0 and 1, dated August 2, 2024 and October 9, 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 August 2, 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 August 2, 2024 and October 9, 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 125661 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)).

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