Our STN: BL 125402/1206

SUPPLEMENT APPROVAL
July 18, 2025

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

Dear Olumade Badejo:

We have approved your request received November 1, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Infusion (Human), 10% with Recombinant Human Hyaluronidase to update the US Prescribing Information (USPI) to add the option for product administration using the cross-referenced HyHub and HyHub Duo Vial Access Devices. The updated sections of the USPI include Section 1 Indications and Usage, Section 2 Dosage and Administration, Section 5 Warnings and Precautions, Section 8 Use in Specific Populations, Section 15 References (deleted), and Patient Information.

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 and Patient Package Insert submitted under amendment 9, dated July 18, 2025.

This is a reminder that as of September 24, 2014, device constituents of combination products may be subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device constituent label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18 and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device constituent, and the device identifiers that have been discontinued for the subject device constituent as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website at http://www.fda.gov/udi.

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 and Patient Package Insert submitted on July 18, 2025. 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 125402 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,

Asha Das, MD
Acting Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research