Our STN: BL 125105/2184

SUPPLEMENT APPROVAL
June 27, 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 August 29, 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% solution, to seek approval of GAMMAGARD LIQUID ERC [immune globulin infusion (human)] 10% solution, for the indication of a replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT00157079, NCT00161993, NCT00546871.

LABELING

We hereby approve the draft content of labeling Package Insert, Patient Package Insert, Instructions for Use submitted under amendment 16, dated June 26, 2025, and the draft carton and container labels submitted under amendment 15, dated June 26, 2025.

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, Patient Package Insert, and Instructions for Use submitted on June 26, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on June 26, 2025, 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 125105 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.

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.

We are waiving the pediatric study requirement for ages birth to less than 2 years. This is because necessary studies are impossible or highly impracticable.

This product is appropriately labeled for use in ages 2 years to 16 years for this indication. Therefore, no additional studies are needed in this pediatric group.

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