Our STN: BL 125325/529

SUPPLEMENT APPROVAL
September 27, 2022

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Dani Sweeney
95 Hayden Avenue
Lexington, MA 02421

Dear Ms. Sweeney:

We have approved your request received March 29, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Alpha-1-Proteinase Inhibitor (Human) [GLASSIA] to replace the 5 µm filter needle (supplied with the product) used for pooling the GLASSIA product before administration, with a filter-less needle (not supplied), in the relevant sections of the U.S. Prescribing Information. The change applies to GLASSIA manufactured at the Takeda Lessines, Belgium facility and the Kamada Beit Kama, Israel facility.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 5, dated September 26, 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, and Instructions for Use submitted on September 26, 2022 . 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 125325/0 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,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research