Our STN: BL 125402/818

SUPPLEMENT APPROVAL
POSTMARKETING REQUIREMENT/
COMMITMENTS FULFILLED
April 7, 2023

Baxalta US Inc.
Attention: Jacqueline Koch
650 East Kendall Street
Cambridge, MA 02142

Dear Ms. Koch:

We have approved your request received March 8, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase to extend the indication of Primary Immunodeficiency Diseases to pediatric patients from 2 years of age ≤ 16 years of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT03277313.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 37, dated April 7, 2023.

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 April 7, 2023. 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)).

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENT

This submission fulfills your postmarketing requirement (PMR) #1, and postmarketing commitment #3 identified in the September 12, 2014 approval letter for BLA STN BL 125402 for Immune Globulin Infusion (Human), 10% with Recombinant Human Hyaluronidase. The requirement and commitment addressed in this submission are as follows:

PMR #1: Deferred pediatric study under PREA for the treatment of primary immunodeficiency in pediatric patients ages 2 – 16 years of age.

Final Protocol Submission: March 1, 2025

Study Completion Date: February 28, 2027

Final Report Submission: July 31, 2027

PMC #3: Baxter commits to establish and maintain a pregnancy registry to assess a) the course and outcome of the pregnancy, b) the development of the fetus/infant at birth, and c) the development of the infant for two years

following birth. The duration of the registry will be six years and will be open to all women who become pregnant while taking HYQVIA.

Final protocol submission date: March 12, 2015

Study/trial completion date: June 12, 2021

Final Report Submission date: November 12, 2021

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

AGREED UPON POSTMARKETING COMMITMENT

POSTMARKETING COMMITMENT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your correspondence of April 4, 2023, as outlined below:

1. A postmarketing, retrospective, pregnancy safety study entitled, “Maternal and infant characteristics and outcomes following exposure to HYQVIA during pregnancy: a case series study based on US claims data” (Protocol TAK-771-4004) t, to further assess safety of HYQVIA during pregnancy. Study milestone dates are as follows:

   Final Protocol Submission: March 3, 2023
   Study/Trial Completion Date: April 15, 2023

   Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 13840, and a cross-reference letter to BLA STN BL 125402 explaining that this protocol was submitted to the IND.

If the information in the final study report supports a change in the labeling, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this

product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN BL 125402 until all requirements and commitments subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act (FDCA) are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

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

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation General Medicine
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research