Our STN: BL 125512/317

SUPPLEMENT APPROVAL
February 10, 2023

Baxalta US Inc.
Attention: Sireesha Alla
500 Kendall Street
Cambridge, MA 02142

Dear Ms. Alla:

We have approved your request received August 11, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for OBIZUR (Antihemophilic Factor (Recombinant), Porcine Sequence) to update Sections 4 (Contraindications) and 6 (Adverse Reactions) of the US Prescribing Information due to observations of a high incidence of anamnestic reactions in patients with Congenital Hemophilia A with Inhibitors based on results from: A Phase 3, Multicenter, Single arm, Open-label Study of the Efficacy and Safety of B-Domain Deleted Recombinant Porcine Factor VIII (BAX 802) in Subjects with Congenital Hemophilia A with Factor VIII Inhibitors Undergoing Surgical or Other Invasive Procedures.

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 submitted BLA 125512/317 under amendment 1, dated February 8, 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 August 11, 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 125512 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,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research