Our STN: BL 125566/607

SUPPLEMENT APPROVAL
PMR/PMC FULFILLED
June 14, 2021

Baxalta US, Inc.
Attention: Kathleen Croal
650 East Kendall Street
Cambridge, MA 02142

Dear Ms. Croal:

We have approved your request submitted and received on May 15, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Antihemophilic Factor (Recombinant) PEGylated [ADYNOVATE®] to include data from completed studies: 261302, 261303, and 261204.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment #23, dated, June 14, 2021.

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 June 14, 2021. 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 BLA 125566/0 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.

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfils your postmarketing requirement PMR# 3 identified in November 13, 2015, approval letter for BLA STN 125566/0. The requirement addressed in this submission is as follows:

3. Deferred pediatric study under PREA for routine prophylaxis to compare the efficacy and safety of two different pharmacokinetics (PK) guided dosing regimens in pediatric patients ages 12 to < 17 years (A phase 3, prospective, randomized, multi-center clinical study comparing the safety and efficacy of ADYNOVATE following PK-guided prophylaxis targeting two different FVIII trough levels in subjects with severe Hemophilia A [clinical study 261303] - **PEDIATRIC COMPONENT ONLY**)**.**

   Final Protocol Submission: September 08, 2015
   Study Completion Date: December 31, 2018
   Final Report Submission: September 30, 2019

FULFILLED POSTMARKETING COMMITMENT

This submission fulfils your post marketing commitments (PMCs) #6 identified in the November 13, 2015, approval letter for BLA STN 125566/0. The PMC addressed in this submission is as follows:

6. A phase 3, prospective, randomized, multicenter clinical study comparing the safety and efficacy of BAX 855 [ADYNOVATE] following PK-guided prophylaxis targeting two different FVIII trough levels in subjects with severe Hemophilia A" [clinical study 261303] – **ADULT COMPONENT ONLY.**

   Final protocol submission date: September 08, 2015
   Study/trial completion date: December 31, 2018
   Final Report Submission date: September 30, 2019

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