Our STN: BL 125574/400

SUPPLEMENT APPROVAL
PMC FULFILLED
January 8, 2021

Bayer HealthCare LLC
Attention: Tina Park
100 Bayer Boulevard
P.O. Box 915
Whippany, NJ 07981-0915

Dear Ms. Park:

We have approved your request submitted March 9, 2020, received March 10, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Antihemophilic Factor (Recombinant), Full Length, to provide the Clinical Study Report (CSR) for Postmarketing Commitment #1 noted in the approval letter for STN BL 125574/0 and to update Section 6 of the Prescribing Information to include information related to inhibitor development in previously untreated patients with hemophilia A.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT01311648. NCT01311648.

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 package insert labeling submitted under amendment #2, dated December 23, 2020.

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. 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.

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/COMMITMENTS

This submission fulfills your postmarketing commitment (PMC) #1 identified in the March 16, 2016, approval letter for STN BL 125774/0 for Antihemophilic Factor (Recombinant), Full Length. The commitment addressed in this submission is as follows:

STN: BL 125574/0

PMC #1: Bayer HealthCare LLC commits to collecting additional safety and efficacy information of KOVALTRY in patients with hemophilia A in a clinical study in 25 previously untreated patients under Protocol 13400 “A multi-center Phase III uncontrolled open-label trial to evaluate safety and efficacy of BAY 81-8973 (KOVALTRY) in children with severe haemophilia A under prophylaxis therapy.”

Final protocol submission: December 20, 2010 (completed)
Study/Clinical trial completion: February 28, 2019
Final Report submission: August 31, 2019

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

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