Our STN: BL 125574/424

SUPPLEMENT APPROVAL
PMC FULFILLED
October 27, 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 April 26, 2021, received April 27, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Antihemophilic Factor (Recombinant), Full Length to include a Clinical Study Report for Postmarketing Commitment (PMC) #2 to support a post-approval labeling supplement for KOVALTRY® and for the addition of data from Study 13400 LEOPOLD Kids Extension on the long-term use of KOVALTRY® in patients from Part A and Part B of the study.

We hereby approve the draft content of labeling Package Insert submitted under amendment 7, dated October 21, 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 October 21, 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 BL 125574 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/COMMITMENTS

This submission fulfills your postmarketing commitment #2 identified in the March 16, 2016, approval letter for BLA STN BL 125574 for Antihemophilic Factor (Recombinant), Full Length. The commitment addressed in this submission is as follows:

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PMC #2 Bayer HealthCare LLC commits to collecting additional safety and efficacy information of KOVALTRY in patients with hemophilia A in an extension clinical study under Protocol 13400 “A multicenter 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
Study/Clinical trial completion: December 31, 2020
Final Report submission: June 30, 2021

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