Our STN: BL 125426/177

SUPPLEMENT APPROVAL
September 25, 2020

Aptevo BioTherapeutics LLC
Attention: Ms. Sally Gould
2401 4th Avenue, Suite 1050
Seattle, WA 98121

Dear Ms. Gould:

We have approved your request submitted and received on February 5, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Coagulation Factor IX (Recombinant) to add an indication for routine prophylaxis to reduce the frequency of bleeding episodes in adults and adolescents ≥ 12 years of age with hemophilia B.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 00768287

LABELING

We hereby approve the draft package insert labeling submitted under amendment 9, dated September 25, 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.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125426/0 at the time of use (prior to marketing) 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.

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 remind you of your outstanding deferred pediatric study requirement in children under 12 years of age for the treatment of hemophilia B (including routine prophylaxis, control and prevention of bleeding episodes and perioperative management) that was put in place with your original approval in 2015 and which was granted a deferral extension on January 20, 2016.

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