Our STN: BL 125426/193

PARTIAL RESCISSION OF APPROVAL
February 17, 2021

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

Dear Ms. Gould:

Please refer to your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act (PHS Act) for Coagulation Factor IX (Recombinant).

We also refer to FDA's letter dated September 25, 2020, for your BLA supplement STN BL 125426/177 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 which was approved.

Upon review of Agency records, we have determined that FDA erred in approving the indication for routine prophylaxis to reduce the frequency of bleeding episodes in adolescents ≥ 12 years of age with hemophilia B on September 25, 2020. As noted below, your product was not eligible to be approved for this particular indication at that time because another licensed product, Baxalta US Inc.'s product, RIXUBIS, Coagulation Factor IX (Recombinant) (BLA 125446) ("RIXUBIS"), had orphan-drug exclusivity blocking such approval. Please note that the indication for routine prophylaxis to reduce the frequency of bleeding episodes in **adults** with hemophilia B is not at issue, and the September 25, 2020 approval for the adult indication remains in effect.

The Orphan Drug provisions of the FD&C Act, 21 U.S.C. §§ 360aa *et seq.*, provide for, among other things, seven years of exclusivity that blocks approval of another applicant's application for the same drug for the same indication. The orphan exclusivity for RIXUBIS is in effect until September 12, 2021, and therefore, your supplement for BLA 125426 to add an indication for routine prophylaxis to reduce the frequency of bleeding episodes in adolescents ≥ 12 years of age with hemophilia B should not have been approved and is rescinded.

FDA is correcting its error to make clear that the approval of your supplement for BLA 125426/177 only covers the indication for routine prophylaxis to reduce the frequency of bleeding episodes in adults with hemophilia B. Therefore, your labeling needs to be revised to remove the exclusivity protected aspect of the indication (i.e., routine

prophylaxis to reduce the frequency of bleeding episodes in adolescents ≥ 12 years of age with hemophilia B). Attached is revised draft labeling for IXINITY, Coagulation Factor IX (Recombinant). We note that any other applications for Coagulation Factor IX (Recombinant) for routine prophylaxis to reduce the frequency of bleeding episodes in adolescents ≥ 12 years of age with hemophilia B currently approved or pending approval prior to the expiration of the above-stated exclusivity on September 12, 2021, will also need to have their labeling updated in accordance with the attached model labeling.

Please submit updated labeling as an amendment to STN BL 125426/193 no later than February 23, 2021. Submit labeling exactly as specified above as a "Supplement - Changes Being Effected" and incorporate all revisions since the last approval of the prescribing information. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should also include annotations that support all proposed changes, including annual reportable changes. Your supplement must include updated content of labeling 21 CFR 601.14(b)] in structured product labeling (SPL) format as described at FDA.gov.

If you have any questions, please contact the Regulatory Project Manager, Catherine Tran at catherine.tran@fda.hhs.gov.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
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