



Our STN: BL 103677/6512

SUPPLEMENT APPROVAL

June 26, 2020

Wyeth Pharmaceuticals LLC
Attention: Dr. Nicole Parker
Pfizer
235 East 42nd Street
New York, NY 10017-7555

Dear Dr. Parker:

We have approved your request submitted and received on August 27, 2014, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Coagulation Factor IX (Recombinant) to include the routine prophylaxis indication in adult and children with hemophilia B (congenital factor IX deficiency or Christmas disease).

We hereby approve the draft package insert labeling submitted under amendment 22, dated June 26, 2020.

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.

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.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

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