

Application Type	Original Application
STN	125574/0
CBER Received Date	December 16, 2014
PDUFA Goal Date	March 16, 2016
Division / Office	DHRR /OBRR
Priority Review	No
Reviewer Name(s)	Megha Kaushal
Review Completion Date / Stamped Date	
Supervisory Concurrence	
Applicant	Bayer HealthCare LLC
Established Name	Antihemophilic Factor (Recombinant), Full Length
(Proposed) Trade Name	KOVALTRY
Pharmacologic Class	Recombinant Full Length
Formulation(s), including Adjuvants, etc	Intravenous Injection
Dosage Form(s) and Route(s) of Administration	Lyophilized Powder in Single Use Vials containing 250, 500, 1000, 2000, and 3000 IU for intravenous use after reconstitution only
Dosing Regimen	<p>Routine Prophylaxis in Adults and Adolescents: 20-40 IU/kg 2 or 3 times per week</p> <p>Routine prophylaxis in Children ≤ 12 years old: 25-50 IU/kg 2 times per week, 3 times per week, or every other day</p> <p>Control and prevention of bleeding episodes and peri-operative management: Dosing determined by calculations provided in the label using body weight and taking into consideration individualized dosing needs.</p>
Indication(s) and Intended Population(s)	On demand treatment and control of bleeding episodes; Perioperative management of bleeding; Routine prophylaxis to reduce the frequency of bleeding episodes in adults and children with Hemophilia A.
Orphan Designated (Yes/No)	No

ADDENDUM TO CLINICAL REVIEW MEMO – LABELING REVIEW

The applicant has made a series of changes to the draft package insert in a series of amendments in response to information requests resulting from review by the CBER Advertising, Promotion, and Labeling Branch, Div. of Hematology Clinical Review, and Div. of Hematology Research Review. The draft package insert submitted by the applicant on 15 March 2016 (attached) has been reviewed by me from the clinical perspective and has been found to be satisfactory.

RECOMMENDATION:

After my review of the draft package insert submitted on 15 March 2016, the BLA may be approved from the clinical perspective.