

Application Type	Original Application
STN	125566/0
CBER Received Date	November 25, 2014
PDUFA Goal Date	November 5, 2015
Division / Office	DHCR /OBRR
Priority Review	No
Reviewer Name(s)	L. Ross Pierce, MD
Review Completion Date / Stamped Date	
Supervisory Concurrence	
Applicant	Baxalta US Inc.
Established Name	Antihemophilic Factor (Recombinant), PEGylated
(Proposed) Trade Name	ADYNOVATE
Pharmacologic Class	Coagulation factor
Formulation(s), including Adjuvants, etc	Intravenous injection
Dosage Form(s) and Route(s) of Administration	Lyophilized Powder for Injectable Solution, Intravenous
Dosing Regimen	Calculated by body weight. Available in 250, 500, 1000, 2000 IU single use vials
Indication(s) and Intended Population(s)	Treatment and Control of bleeding episodes in adolescents and adults age 12 years and above with hemophilia A. Routine prophylaxis to reduce the frequency of bleeding episodes in adolescents and adults age 12 years and above with hemophilia A.

## **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, Drs. Omokaro, Pierce of the Div. of Hematology Clinical Review, and Dr. Peng of the Div. of Hematology Research Review. The draft package insert submitted by the applicant on 15 October 2015 (attached) has been reviewed by me from the clinical perspective and has been found to be satisfactory.

### **RECOMMENDATION:**

Based on the clinical review memo prepared by Dr. Omokaro of the Div. of Hematology Clinical Review, as edited by Dr. Bindu George and myself, and my review of the draft package insert submitted on 15 October 2015, the BLA may be approved from the clinical perspective.