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*APPLICATION NUMBER:*

**208194Orig1s000**

**MEDICAL REVIEW(S)**

## CLINICAL REVIEW

Application Type	NDA (505(b)(2))
Application Number	208194 Supporting Document 1
Priority or Standard	Standard
Submit Date	February 13, 2015
Received Date	February 13, 2015
PDUFA Goal Date	December 13, 2015
Division	Division of Hematology Products
Reviewer Name	Andrew Dmytrijuk M.D.
Review Completion Date	November 17, 2015
Established Name	Bendamustine Hydrochloride Injection
Trade Name	Bendeka®
Therapeutic Class	Alkylating Drug
Applicant	Eagle Pharmaceuticals Inc. 50 Tice Blvd. Suite 315 Woodcliff Lake, NJ 07677
Formulation	Injection
Dosing Regimen	100mg/4mL (25mg/mL)
Indication	Treatment Of Patients With Chronic Lymphocytic Leukemia (CLL). Treatment Of Patients With Indolent B-Cell Non-Hodgkin Lymphoma (NHL) That Has Progressed During Or Within Six Months Of Treatment With Rituximab Or A Rituximab-Containing Regimen.
Intended Population	Patients With Chronic Lymphocytic Leukemia and Indolent B-Cell Non-Hodgkin Lymphoma

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