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RESEARCH**

APPLICATION NUMBER:

208194Orig1s000

PHARMACOLOGY REVIEW(S)

MEMORANDUM

Date: November 10, 2015
From: Christopher M. Sheth, PhD
Pharmacology/Toxicology Supervisor
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)
Re: Approvability for Pharmacology and Toxicology
NDA: 208194
Drug: Bendamustine hydrochloride
Indications: Chronic lymphocytic leukemia and B cell non-Hodgkin lymphoma
Applicant: Eagle Pharmaceuticals, Inc.

I have examined the pharmacology/toxicology supporting review for bendamustine HCl conducted by Dr. Manning. I concur with Dr. Manning's conclusion that bendamustine HCl may be approved for the proposed indication.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CHRISTOPHER M SHETH
11/10/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application number: NDA 208194
Supporting document/s: 1
Applicant's letter date: February 12, 2015
CDER stamp date: February 13, 2015
Product: Bendamustine hydrochloride (HCl)
Indication: Chronic lymphocytic leukemia (CLL)
B cell non-Hodgkin lymphoma (NHL)
Applicant: Eagle Pharmaceuticals, Inc (EPI)
Review Division: Division of Hematology Oncology Toxicology
(DHOT) for Division of Hematology Products
(DHP)
Reviewer: Michael L Manning, PhD (DHOT)
Supervisor/Team Leader: Christopher M Sheth, PhD (DHOT)
Division Director: John Leighton, PhD, DABT (DHOT)
Ann Farrell, MD (DHP)
Project Manager: Laura Wall, MS, APHN, OCN

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