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APPLICATION NUMBER:

205580Orig1s000

NON-CLINICAL REVIEW(S)

**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 205580

Supporting document/s: 1 (original) and 8 (resubmission after refuse to file)

Applicant's letter date: September 6, 2013

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Product: Bendamustine HCl

Indication: Chronic Lymphocytic Leukemia (CLL)
Non-Hodgkin's lymphoma (NHL)

Applicant: Eagle Pharmaceuticals, Inc. (EPI)

Review Division: Division of Hematology Oncology Toxicology (DHOT) for Division of Hematology Products (DHP)

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