

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209191Orig1s000

NON-CLINICAL REVIEW(S)

MEMORANDUM

Date: July 5, 2018

To: File for ND 209191

From: Emily Place, PhD MPH
Pharmacology-Toxicology Reviewer
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Through: Christopher Sheth, PhD
Pharmacology-Toxicology Supervisor
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Subject: NDA 209191

NDA: 209191

Drug: Bortezomib for Injection

Indication: Treatment of patients with multiple myeloma

The current submission, Supporting Document 30 (eCTD Sequence 0030) for NDA 209191, is a resubmission/Class 1 for Bortezomib for Injection. Bortezomib is a small molecule inhibitor of the chymotrypsin-like activity of the 20S proteasome. Bortezomib was approved on May 13, 2003 (NDA 021602) for the treatment of 1) multiple myeloma (MM) 2) treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy. [REDACTED] (b) (4)

[REDACTED]

Recommendation: There are no pharmacology/toxicology issues that would preclude approval of NDA 209191.

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/s/

EMILY J PLACE
07/05/2018

CHRISTOPHER M SHETH
07/05/2018

MEMORANDUM

Date: November 1, 2017

To: File for ND 209191

From: Emily Place, PhD MPH
Pharmacology-Toxicology Reviewer
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Through: Christopher Sheth, PhD
Pharmacology-Toxicology Supervisor
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Subject: NDA 209191

NDA: 209191

Drug: Bortezomib for Injection

Indication: Treatment of patients with multiple myeloma

The current submission, Supporting Document 18 (eCTD Sequence 0018) for NDA 209191, is a resubmission/Class 1 for Bortezomib for Injection. Bortezomib is a small molecule inhibitor of the chymotrypsin-like activity of the 20S proteasome. Bortezomib was approved on May 13, 2003 (NDA 021602) for the treatment of 1) multiple myeloma (MM) 2) treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy. (b) (4)

[REDACTED]

Recommendation: There are no pharmacology/toxicology issues that would preclude approval of NDA 209191.

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/s/

EMILY J PLACE
11/01/2017

CHRISTOPHER M SHETH
11/01/2017

MEMORANDUM

Date: March 22, 2017

To: File for ND 209191

From: Emily Place, PhD MPH
Pharmacology-Toxicology Reviewer
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Through: Christopher Sheth, PhD
Pharmacology-Toxicology Supervisor
Division of Hematology Oncology Toxicology (DHOT)
Office of Hematology and Oncology Products (OHOP)

Subject: NDA 209191

NDA: 209191

Drug: Bortezomib for Injection

Indication: Treatment of patients with multiple myeloma

The current submission, Supporting Document 3(eCTD Sequence 0003) for NDA 209191, is (b) (4) (b) (4) for Bortezomib for Injection. Bortezomib is a small molecule inhibitor of the chymotrypsin-like activity of the 20S proteasome. Bortezomib was approved on May 13, 2003 (021602) for the treatment of 1) multiple myeloma (MM) 2) treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy. (b) (4) the Applicant is proposing a new 2.5 mg/vial strength of Bortezomib for Injection. During labeling discussions, the applicant inquired to the basis for the recommendation regarding male contraception. The agency proposed the duration of contraception based on current thinking which is 3 months plus 5 half-lives which is approximately 4 months based on genotoxic drugs.

(b) (4)

Recommendation:

There are no pharmacology/toxicology issues for NDA 209191 to preclude approval of the drug for the proposed change in strength.

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/s/

EMILY J PLACE
03/22/2017

CHRISTOPHER M SHETH
03/23/2017