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RESEARCH**

APPLICATION NUMBER:

215331Orig1s000

SUMMARY REVIEW

Division Director Summary Review

Date	July 7, 2022
From	Nicole Gormley, MD
Subject	Division Director Summary Review
NDA/BLA # and Supplement #	215331
Applicant	MAIA Pharmaceuticals, Inc.
Date of Receipt	September 27, 2021
PDUFA Goal Date	July 27, 2022
Proprietary Name	Bortezomib Injection
Dosage Form(s)/Strength	Injection/ 3.5 mg/3.5 mL and 3.5mg/ 1.4mL
Applicant Proposed Indication(s)	<ul style="list-style-type: none">• Treatment of adult patients with multiple myeloma• Treatment of adult patients with mantle cell lymphoma
Action or Recommended Action:	Approval

This Division Director Summary Review is based on review of the following materials:

- CDTL Review by Sherita McLamore, PhD
- Clinical and Labeling Review by Candis Morrison, PhD, CRNP; Bindu Kanapuru, MD; and Elizabeth Everhart, MSN, ACNP

The CDTL, clinical team, and Associate Director for Labeling recommend approval of this application. Please refer to their reviews for further details.

Regulatory Recommendation: Approval

Nicole Gormley, MD

Director, Division of Hematologic Malignancies II

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/s/

NICOLE J GORMLEY
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