CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210259Orig1s000

MULTI-DISCIPLINE REVIEW

Summary Review
Office Director
Cross Discipline Team Leader Review
Clinical Review
Non-Clinical Review
Statistical Review
Clinical Pharmacology Review

NDA/BLA Multi-disciplinary Review and Evaluation

Application Type	NDA, 505(b)(1)
Application Number(s)	210259
Priority or Standard	Priority
Submit Date(s)	June 13, 2017
Received Date(s)	June 13, 2017
PDUFA Goal Date	February 13, 2018 (**expedited date of October 31, 2017**)
Division/Office	CDER/OHOP/DHP
Review Completion Date	October 26, 2017
Established Name	Acalabrutinib
(Proposed) Trade Name	CALQUENCE
Pharmacologic Class	Kinase inhibitor
Code name	ACP-196
Applicant	Acerta Pharma B.V.
Formulation(s)	hard shell capsule
Dosing Regimen	100 mg orally approximately every 12 hours
Applicant Proposed Indication(s)/Population(s)	Treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
Recommendation on Regulatory Action	Accelerated Approval
Recommended Indication(s)/Population(s) (if applicable)	Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

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