Office of Clinical Pharmacology Review Memorandum

NDA Number	NDA 202806 Efficacy Supplement 25
Link to EDR	\\CDSESUB1\EVSPROD\nda202806\0386
Submission Date	08/24/2022
Submission Type	Efficacy Supplement
Brand Name	Tafinlar Capsules
Generic Name	Dabrafenib
Dosage Form and Strength	Capsules,
Route of Administration	Oral
Proposed Indication	in combination with trametinib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with BRAF V600E mutation who require systemic therapy.”
Applicant	Novartis
Associated IND	IND 105032 dabrafenib IND 113557 dabrafenib and trametinib IND 117898 dabrafenib (b) (4)
OCP Review Team	Banu Zolnik, Ph.D.
OCP Team Lead	Hong Zhao, Ph.D.

This Supplemental NDA cross references to NDA 217514 Tafinlar (dabrafenib) tablets for oral suspension. Refer to the completed Clinical Pharmacology review in the Assessment Aid for NDA 217514 and NDA 217513.

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/s/

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03/03/2023 02:51:45 PM

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