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*APPLICATION NUMBER:*

**211225Orig1s000**

**CLINICAL REVIEW(S)**

Clinical Memorandum  
NDA Review Ceritinib  
New Dosage Form: Tablets

NDA 211225, SDN 1

Received May 18, 2018

Sponsor: Novartis Pharmaceutical Corp.

Product: Zykadia (ceritinib) Tablets, 150 mg

Clinical Reviewer: Barb Scepura

Clinical Team Leader: Erin Larkins

Subject:

On May 18, 2018, Novartis submitted a New Drug Application (NDA) for a new dosage form for ZYKADIA® (ceritinib), 150 mg film-coated tablet (FCT) as a bioequivalent, interchangeable, replacement for ZYKADIA® (ceritinib) 150 mg capsule. Ceritinib is currently approved for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

NDA Submission:

The submission contains three bioequivalence studies. For details on bioequivalence between capsule and tablet formulations, please see the reviews by the Clinical Pharmacology team and the Chemistry Manufacturing and Controls (CMC) team. No new clinical data was submitted. The label was amended to include information specific to the new tablet formulation, food effects, and drug-drug interactions. Editorial revisions were made throughout the label for clarity.

Pediatric Waiver:

Ceritinib has orphan drug designation for treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test, this designation applies to both the capsule and tablet formulations.

Conclusion and Recommendation: No clinical data was submitted. The clinical team defers to the recommendations of the Clinical Pharmacology Team and the CMC team.

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