

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210661Orig1s000

OFFICE DIRECTOR MEMO

Division Director Review

Date	June 28, 2024
From	Erin Larkins, M.D., Director (Acting), DO2
NDA	210661 (resubmission)
Applicant	AVYXA Holdings LLC
Date of Submission	03/29/2024
PDUFA Goal Date	05/29/2024
Proprietary Name	N/A
Established or Proper Name	Pemetrexed for injection
Dosage Form(s)	For Injection: 100 mg or 500 mg pemetrexed equivalent to 118.3 mg or 591.5 mg pemetrexed dipotassium as lyophilized powder in single-dose vial
Indication(s)	Pemetrexed for Injection is a folate analog metabolic inhibitor indicated: • in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, nonsquamous NSCLC. • as a single agent for the maintenance treatment of patients with locally advanced or metastatic, nonsquamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. • as a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy. Limitations of Use: Pemetrexed for Injection is not indicated for the treatment of patients with squamouscell, non-small cell lung cancer. • initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

Recommendation is for Approval for the above indications. See CDTL review memo for details regarding this application.

This application was cleared for action and determined to be eligible for an approval action from a 505(b)(2) perspective.

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/s/

ERIN A LARKINS
06/28/2024 11:55:13 AM