

Office of Clinical Pharmacology-- Review Memo

Application Type	NDA
Application Number(s)	209905/S-001
Priority or Standard	Standard
SDN#	34
Submit Date(s)	6/18/2020
PDUFA Goal Date	4/18/2021
Division/Office	Division of Psychiatry/Office of Neuroscience
Established/Proper Name	Amphetamine sulfate
(Proposed) Trade Name	Evekeo ODT
Pharmacologic Class	CNS stimulant
Applicant	Arbor Pharmaceuticals LLC
Dosage form	Orally Disintegrating Tablets
Applicant Proposed Indication(s)/Population(s)	Treatment of ADHD/Pediatric patients >4 years of age
OCP Review Team	Li Tan, Luning (Ada) Zhuang
OCP Final Signatory	Mehul Mehta Div. Director, Div. of Neuropsychiatry Pharmacology OCP

The office of clinical pharmacology (OCP) review was completed in the previous cycle and was submitted in DARRTS on 12/21/18. There is no additional or new information related to OCP in the resubmission and our assessment has not changed.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LI TAN
03/18/2021 03:38:35 PM
OCP Memo

LUNING ZHUANG
03/18/2021 03:48:50 PM

MEHUL U MEHTA
03/18/2021 03:51:12 PM