Clinical Review Memo

From	Cathy Southammakosane, MD, Medical Officer, Division of Psychiatry (DP) Bernard Fischer, MD, Deputy Director/Clinical Team Lead, DP
Subject	Clinical Review Memo
NDA/BLA # and Supplement#	NDA 209905/S-001
Applicant	Arbor Pharmaceuticals LLC
Date of Submission	June 18, 2020
PDUFA Goal Date	April 18, 2021
Proprietary Name (code name)	Evekeo
Established or Proper Name	Amphetamine sulfate immediate release (IR)
Dosage Form(s) and strengths	Orally disintegrating tablet (ODT)
Applicant Proposed Indication(s)/Population(s)	Treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients age 3 to 17 years of age
Applicant Proposed Dosing Regimen(s)	2.5 mg once to twice daily (with this supplement); 5 mg once to twice daily; 10 mg once to twice daily; 15 mg once to twice daily; 20 mg once to twice daily
Recommendation on Regulatory Action	Approve
Recommended Indication(s)/Population(s)	Treatment of ADHD in pediatric patients age 3 to 17 years of age
Recommended Dosing Regimen(s)	2.5 mg once to twice daily; 5 mg once to twice daily; 10 mg once to twice daily; 15 mg once to twice daily; 20 mg once to twice daily

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Amphetamine sulfate immediate release orally disintegrating tablet

Arbor Pharmaceuticals has submitted a 505(b)(2) NDA supplement for amphetamine sulfate IR ODT 2.5 mg. Amphetamine sulfate IR ODT is a stimulant medication approved in 2019 for use in pediatric patients ages 6 to 17 years with ADHD; the listed drug (LD) amphetamine sulfate IR was approved in 2012. Relying upon the LD, the indication for use will be broadened to include patients down to age 3 years; the Sponsor is fulfilling a postmarketing requirement to develop an age-appropriate drug formulation (2.5 mg tablet) for this younger pediatric population (ages 3 to <6 years). No clinical data was submitted with this supplement, so there is no clinical data for review. At the time of this memo, the Prescribing Information is being finalized. In the draft label, Section 2.2: Dosage Information, the Applicant added dose recommendations for patients 3 to 5 years of age beginning at 2.5 mg daily and titrated in increments of 2.5 mg weekly. Additionally, the following clinical recommendations for changes to the proposed label have been made to the Applicant: in Section 2.2 Dosage Information, for patients 6 to 17 years of age, dose titration can be made in increments of 2.5 or 5 mg weekly to allow for more flexibility; and in Section 8.4 Pediatric Use, the pediatric age range of 3 to 17 years was added to align with the indicated population. Please refer to the primary review conducted by Chemistry, Manufacturing, and Controls for more information.

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/s/

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03/19/2021 07:18:09 AM

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03/19/2021 09:09:32 AM
Supervisory Physician