Evekeo ODT™ (amphetamine sulfate) – Expanded indication, new strength

- On April 16, 2021, the FDA approved Arbor Pharmaceuticals' Evekeo ODT (amphetamine sulfate), for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 3 to 17 years of age.
    - Evekeo ODT was previously approved for this indication in patients 6 to 17 years of age.
    - Evekeo ODT is a Schedule II controlled substance.
- Evekeo ODT carries a boxed warning for abuse and dependence.
- In addition to the expanded indication, the FDA also approved a new strength (2.5 mg) of Evekeo ODT.
- The recommended starting dosage of Evekeo ODT in pediatric patients 3 to 5 years of age is 2.5 mg orally daily in the morning. If necessary, an additional dose can be administered after 4 to 6 hours. The dosage should be titrated in increments of 2.5 mg at weekly intervals depending on response and tolerability.
    - Refer to the Evekeo ODT drug label for dosing in pediatric patients 6 to 17 years of age.
    - Switching from Evekeo to Evekeo ODT can be done on a milligram-per-milligram basis. Evekeo ODT should not be substituted for other amphetamine products on a milligram-per-milligram basis because of different amphetamine salt compositions and differing pharmacokinetic profiles.
- Arbor Pharmaceuticals' launch plans for Evekeo ODT 2.5 mg are pending.