QuilliChew ER™ (methylphenidate) – New Drug Approval

- On December 7, 2015, Pfizer and Tris Pharma announced the FDA approval of QuilliChew ER (methylphenidate), a central nervous system (CNS) stimulant, for the treatment of attention deficit hyperactivity disorder (ADHD).
  - QuilliChew ER is a Schedule II controlled substance.
- QuilliChew ER’s approval was based on a laboratory classroom study conducted in 90 pediatric patients (6 – 12 years of age) with ADHD. Patients received QuilliChew ER or placebo. The attention and behavior of patients were evaluated using the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) rating scale.
  - The average of treatment effects across all time points (0.75 – 13 hours post-dose) for QuilliChew ER was statistically significantly superior to placebo [SKAMP scores: difference = -7.0 (QuilliChew ER, 12.1; placebo, 19.1); 95% confidence interval, -10.9, -3.1].
- Similar to other CNS stimulants, QuilliChew ER carries a boxed warning for abuse and dependence.
- QuilliChew ER is contraindicated with concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days because of the risk of hypertensive crisis.
- Other warnings and precautions for QuilliChew ER include serious cardiovascular reactions; blood pressure and heart rate increases; psychiatric adverse reactions; priapism; peripheral vasculopathy, including Raynaud’s phenomenon; long-term suppression of growth; and risks in patients with phenylketonuria.
- The most common adverse events (≥ 5% and twice the rate of placebo) with methylphenidate use were decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, appetite weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- The recommended starting dose of QuilliChew ER for patients > 6 years of age is 20 mg chewed orally once daily in the morning.
  - The dosage may be titrated up or down in weekly increments of 10 mg, 15 mg, or 20 mg per day.
  - The maximum daily dose is 60 mg.
  - If switching from another methylphenidate product, use QuilliChew ER’s recommended dosage. Do not switch on a milligram-to-milligram basis.
- Methylphenidate is also available under the brand name Quillivant XR®, as an extended-release oral suspension and either branded or generically in various other oral and transdermal formulations.
- Pfizer’s plans to launch QuilliChew ER in the first quarter of 2016. QuilliChew ER will be available as 20 mg, 30 mg, and 40 mg extended-release chewable tablets.