FDA Update, Attention-Deficit/Hyperactivity Disorder (ADHD)

New ADHD medications target patients who have trouble swallowing pills

by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Division of Psychiatry Products

The Food and Drug Administration (FDA) recently approved three new treatment choices for pediatric patients 6 years and older with attention-deficit/hyperactivity disorder (ADHD). All are oral extended-release pediatric formulations:

- Adzenys XR-ODT (amphetamine), approved Jan. 27, is the first extended-release orally disintegrating tablet for the treatment of ADHD.
- QuilliChew ER (methylphenidate hydrochloride), approved Dec. 4, 2015, is the first chewable extended-release ADHD tablet. QuilliChew XR can be chewed or swallowed whole.
- Dyanavel XR (amphetamine), approved Oct. 19, 2015, is the first extended-release amphetamine-based oral suspension.

Each of these formulations may be useful for patients who are unable or have difficulty swallowing tablets or capsules. Patient compliance may be enhanced because these extended-release medications are taken once daily.

As part of the approvals for these formulations, the FDA is requiring studies for patients 4-5 years of age.