**QuilliChew ER — Extended-Release Chewable Methylphenidate Tablets**

The FDA has approved a once-daily, extended-release chewable tablet formulation of methylphenidate (QuilliChew ER — Pfizer) for treatment of attention-deficit/hyperactivity disorder (ADHD). It is the first long-acting chewable formulation of the drug to be marketed in the US. Immediate-release chewable methylphenidate tablets (Methylin, and generics) have been available since 2003.1

**METHYLPHENIDATE** — Short-acting methylphenidate formulations are effective for treatment of ADHD, but their 3-5 hour duration of action usually requires mid-day dosing in school, which children may find disruptive or stigmatizing. Long-acting methylphenidate preparations have therefore become the mainstay of clinical practice. Most long-acting formulations are available only as tablets or capsules that many children find difficult to swallow. Some capsules can be opened and their contents sprinkled on applesauce. All methylphenidate products are Schedule II controlled substances.

**THE NEW FORMULATION** — QuilliChew ER is available as tablets containing 15% methylphenidate HCl and 85% methylphenidate bound to sodium polystyrene sulfonate particles; they contain a mixture of 30% immediate-release and 70% extended-release methylphenidate. In a pharmacokinetic study in healthy adults comparing a single 40-mg dose of QuilliChew ER with two 20-mg doses of immediate-release chewable methylphenidate, the AUC of methylphenidate with QuilliChew ER was within the 80% to 125% bioequivalence acceptance standard, but the Cmax was 20% lower and the AUC was 11% lower than those with immediate-release methylphenidate.2

**CLINICAL STUDIES** — Approval of the new formulation was based on the results of an unpublished, randomized trial (summarized in the package insert) in 90 children 6-12 years old with ADHD who were titrated to an optimal dose (max 60 mg/day) of QuilliChew ER over 6 weeks, followed by 1 week of treatment with either the active drug or placebo. After the 1-week treatment period, the children were evaluated using the SKAMP-Combined score,
which measures ADHD symptoms in a laboratory school setting, at 7 time points between 0.75 and 13 hours post-dose. SKAMP-Combined scores were significantly better with the active drug than with placebo at 0.75, 2, 4, and 8 hours post-dosing, but not at 10, 12, or 13 hours. No head-to-head trials are available comparing the new formulation to other formulations of methylphenidate or other stimulants.

**DOSAGE AND ADMINISTRATION —** The recommended starting dosage of QuilliChew ER in patients ≥6 years old is 20 mg once daily in the morning with or without food. The daily dose can be titrated at weekly intervals by 10, 15, or 20 mg (20- and 30-mg tablets are scored) to a maximum dose of 60 mg.

**CONCLUSION —** QuilliChew ER, a once-daily methylphenidate chewable tablet, provides another option for children with ADHD who are unable to swallow tablets or capsules. How it compares to other long-acting methylphenidate products in efficacy and adverse effects remains to be determined.