



FDA Update, News Articles

FDA OKs imaging tool for evaluating VUR without radiation exposure

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

The Food and Drug Administration approved Lumason (sulfur hexafluoride) for use with ultrasonography for the evaluation of suspected or known vesicoureteral reflux (VUR).

Children with VUR may require repeated imaging of the urinary tract. Lumason is administered intravesically at the time of ultrasound, enabling imaging without radiation exposure.

The determination of effectiveness for this indication in pediatric patients was based on clinical information from two published controlled studies of a total of 411 pediatric patients (217 males and 194 females) ages 2 days to 13 years. In each study, ultrasound images with Lumason compared favorably with reference standard images (radiographic voiding cystourethrogram [VCUG]). The published studies both note that, similar to traditional VCUG, the results of ultrasound with Lumason may be operator dependent.

The determination of safety of ultrasound with Lumason was based on published literature describing its use in over 6,000 pediatric patients; no adverse events were reported.

Earlier identification and treatment, including surgical ureteral correction of high-grade VUR, may interrupt the progression to long-term consequences, such as reflux nephropathy, renal hypertension and end stage renal disease.

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