

Oral Soluble Film by Aquestive Therapeutics to treat epilepsy Syndrome

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Aquestive Therapeutics got acceptance of New Drug Application from US FDA for Clobazam Oral Soluble Film to Treat Lennox-Gastaut Syndrome

Aquestive Therapeutics, Inc. is a specialty pharmaceutical company that advances and commercializes medicines to solve critical healthcare problems.

The company announced that the U.S. Food and Drug Administration (FDA) have accepted for review the company's New Drug Application for clobazam Oral Soluble Film (clobazam OSF).

Clobazam OSF is used for supportive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years of age or older.

LGS accounts for about four percent of all cases of childhood epilepsy.

The PDUFA (Prescription Drug User Fee Act) target date for completion of the FDA review is the third-quarter of 2018.

Clobazam OSF is administered using Aquestive's proprietary PharmFilm drug delivery technology.

Similar in size and thickness to a stamp, Aquestive's PharmFilm dissolves instantly after being placed on the tongue and can be administered without water, among other benefits.

Two multicenter controlled studies were conducted to evaluate the bioequivalence of clobazam OSF with clobazam tablets, a benzodiazepine currently on market, at the same dosage strengths.

Based on the studies, clobazam OSF was demonstrated to be bioequivalent to clobazam tablets and have comparable safety.