DIVISION SIGNATORY REVIEW

Application Type	505(b)(2)
Application Number	NDA 216986 S-009
PDUFA Goal Date	02/20/2026
Division/Office	Division of Imaging and Radiation Medicine/Office of Specialty Medicine
Signatory Name	A. Alex Hofling
Review Completion Date	2/20/2026
Established/Proper Name	Gadopiclenol
Trade Name	Elucirem
Applicant	Guerbet LLC
Dosage Form	Injection
Recommended Dosing Regimen	0.05 mmol/kg actual body weight (equivalent to 0.1 mL/kg) administered intravenously at approximately 2 mL/sec
Recommended Indications	ELUCIREM is indicated in adult and pediatric patients, including term neonates, for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in: • the central nervous system (brain, spine, and associated tissues) • the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system)
Recommended Regulatory Action	Approval

The sponsor of NDA 216986 for Elucirem (gadopiclenol) injection has submitted an efficacy supplement to extend the current magnetic resonance imaging (MRI) indications for adults and pediatric patients aged 2 years and older to include younger pediatric patients down to birth, including term neonates. This submission included the final report of Study GDX-44-015, which was conducted to address the Pediatric Research Equity Act (PREA) postmarketing requirement (PMR) established for pediatric patients from birth to less than 2 years of age at the time of initial NDA approval in September of 2022. Study GDX-44-105 was conducted in this population primarily for pharmacokinetic (PK) analysis of the currently labeled 0.05 mmol/kg dose with additional secondary analyses of imaging results and safety. These analyses were intended to support extrapolation of indications previously approved in adults and pediatric patients 2 years of age and older to younger pediatric patients down to birth.

Review by the Office of Clinical Pharmacology concluded that PK data collected in Study GDX-44-105 as well as related population PK modeling and simulation demonstrated a profile similar to other FDA-approved gadolinium-based contrasts (GBCAs) with comparable gadopiclenol

exposure in patients 2 years of age and older and younger pediatric patients down to birth. These results support the extrapolation approach and the proposed expansion of indications down to birth at the currently recommended weight-based dosing of 0.05 mmol/kg.

Per the review by the clinical team, imaging effectiveness data of gadopiclenol MRI in the central nervous system (CNS) and body from Study GDX-44-105 were limited by sample size and other methodological weaknesses but demonstrated expected trends for improvement in lesion visualization on combined versus pre-contrast images, further supporting the PK-based extrapolation. Available safety data from Study GDX-44-105 did not demonstrate a new safety signal compared to the profile established in adults and older children.

Recommendations of the Associate Director for Labeling appropriately incorporate advice from the review team, including the Division of Medication Error Prevention and Analysis, Division of Pediatrics and Maternal Health, and Office of Prescription Drug Promotion. Addition of the phrase, "including term neonates", in the indications statement is consistent with other FDA-approved GBCAs and aligns with the added statement in Section 8.4 that safety has not been established in preterm neonates.

Per the findings of the multidisciplinary review team, Study GDX-44-105 adequately supports expansion of the current indications in adults and pediatric patients 2 years of age and older to younger pediatric patients down to birth, including term neonates. The FDA Pediatric Review Committee concurred with this conclusion, the related PMR is considered fulfilled, and approval of this supplemental NDA is recommended.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

AUGUST A HOFLING
02/20/2026 09:12:27 AM