

POST MARKETING COMMITMENTS

Product Compound	Description of Commitment	NDA Number	Agreement Date	Project Completion Date	Status
Tralement NDA	A randomized controlled trial of Tralement versus a fixed dose manganese-free combination trace element product to evaluate manganese in patients receiving long-term parenteral nutrition.	NDA 209376 (PMR 3877-01)	06/2024 (Study Completion Date)	03/2025 (Final Report Submission to FDA)	Delayed
Injectafer NDA	Conduct a randomized, placebo-controlled trial in pediatric patients age birth to <18 years with iron deficiency and symptomatic heart failure.	NDA 203565 (S-20) (PMR 4402-1)	June 2026 (Study Completion Date)	March 2027 (Final Report Submission to FDA)	Pending