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FDA OKs first injectable fish oil triglyceride emulsion for parenteral nutrition

by from the Food and Drug Administration's Division of Gastroenterology and Inborn Errors Products, Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, and Office of Pediatric Therapeutics

The Food and Drug Administration (FDA) has approved Omegaven (fish oil triglycerides) injectable emulsion for intravenous use as a source of calories and fatty acids for pediatric patients with parenteral nutrition-associated cholestasis (PNAC).

PNAC, a complication of parenteral nutrition (PN), is defined as persistent elevation in direct bilirubin and is associated with morbidity and mortality due to liver injury. Omegaven will address the need for an alternative parenteral source of fatty acids. The safety and effectiveness of Omegaven have not been established for prevention of PNAC in pediatric patients.

The FDA reviewed data from two investigator-initiated prospective, open-label, single-center studies in neonates (including preterm neonates), infants and young children with PNAC comparing the efficacy and safety of Omegaven to retrospective data from patients receiving a soybean oil-based lipid emulsion as part of their PN regimen. Although the studies were not adequately designed and powered to demonstrate noninferiority or superiority of Omegaven to the comparator, the data were used to compare patients' growth with standardized growth curves. The results, together with generally accepted scientific knowledge of the caloric content of long-chain fatty acids, support Omegaven as a source of calories and fatty acids in pediatric patients with PNAC.

No new safety issues were seen with Omegaven when compared to the generally known safety profile of other parenteral lipid preparations.

A post-approval longitudinal cohort study will assess the potential risk of essential fatty acid deficiency, including neurodevelopmental assessments, and life-threatening pulmonary lipid accumulation with use of Omegaven in patients with PNAC compared to controls.

Resources

- Omegaven drug label
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