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FDA Update, Gastroenterology, Nutrition, Pharmacology

FDA approves drug to treat active Crohn's disease in pediatric patients

by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Division of Gastroenterology and Inborn Errors Products

The Food and Drug Administration has approved Entocort EC (budesonide) to treat Crohn's disease (CD) in pediatric patients, making it the first drug approved for use in children with active disease.

Entocort EC (budesonide) was approved on April 29 for the treatment of mild to moderate active CD involving the ileum and/or the ascending colon in patients 8 years of age and older who weigh more than 25 kilograms.

Use of Entocort EC capsules in this age group is supported by evidence from adequate and well-controlled studies in adults, with additional data from two clinical studies in 149 pediatric patients treated up to eight weeks and one pharmacokinetic study in eight pediatric patients.

The safety and effectiveness of Entocort EC have not been established in pediatric patients younger than 8 years of age or for the maintenance of clinical remission of mild to moderate CD. An open-label study to evaluate the safety and tolerability of Entocort EC as maintenance treatment in pediatric patients ages 5-17 years did not establish the safety and efficacy of maintenance of clinical remission. Pediatric patients with CD have a 17% higher mean systemic exposure and cortisol suppression than adults with CD. Systemic corticosteroids, including Entocort EC, may cause a reduction of growth velocity in pediatric patients.