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Dear Doctor,

TRI-MED is the proud sponsor of Alinia (nitazoxanide) in Australia. It has been Designated an Orphan Drug in Australia since 1999 under the trade name "Cryptaz". It is available in Australia under the TGA's Special Access Scheme. Please find below an FDA "Talk Paper" on Alinia.

FDA APPROVES NEW TREATMENT FOR PARASITIC INFECTIONS IN PEDIATRIC PATIENTS

The Food and Drug Administration (FDA) today announced the approval of Alinia (*nitazoxanide*) for Oral Suspension for the treatment of diarrhea caused by two parasitic infections, cryptosporidiosis and giardiasis, in pediatric patients one through 11 years of age. To date, the safety and effectiveness of Alinia has not been established in HIV positive or immunodeficient patients.

Alinia is the first drug product approved specifically for treatment of cryptosporidiosis and the only drug approved for treatment of giardiasis in this age group that would be available in suspension. According to the Centers for Disease Control and Prevention some 4000 patients in the United States are infected by cryptosporidiosis.

Cryptosporidiosis is an illness caused by the protozoan *Cryptosporidium parvum* and characterized by diarrhea, abdominal cramps, loss of appetite, low-grade fever, nausea and vomiting. Infected persons may be asymptomatic, experience acute diarrhea, or be ill with persistent diarrhea that may continue for several weeks.

The disease can be prolonged and life-threatening in severely immunocompromised individuals. The disease has been associated with malnutrition, impaired growth, and death in children in developing countries.

Giardiasis is an illness caused by the protozoan *Giardia lamblia* and characterized by diarrhea, abdominal cramps, bloating, weight loss, or malabsorption. Disease manifestations of giardiasis range from asymptomatic to fulminant diarrhea and malabsorption. Giardiasis has been associated with impaired growth in children in developing countries.

FDA based its approval of Alinia on the results of controlled clinical studies that showed that a statistically significantly higher percentage of patients suffering from diarrhea caused by cryptosporidiosis and giardiasis treated with Alinia showed signs of clinical improvement than patients who did not receive Alinia.

Two double-blind controlled studies in pediatric patients with diarrhea caused by *Cryptosporidium parvum* were conducted. In the first study, conducted as an out-patient study of pediatric patients age one - 11 years, 88 percent of patients receiving Alinia responded, compared to 38 percent given placebo. In the second study, an in-patient study of malnourished pediatric patients age 12-35 months, 56 percent of patients receiving Alinia responded, compared to 23 percent given placebo.

In a randomized, controlled study conducted in pediatric patients ages 24-47 months with diarrhea caused by *Giardia lamblia*, 85 percent of patients who received a course of treatment with Alinia responded compared to 80 percent who received a course of treatment with metronidazole.

In controlled and uncontrolled clinical studies of 613 pediatric patients not infected with HIV who received Alinia for Oral Suspension, the most frequent adverse events reported in association with Alinia were abdominal pain, diarrhea, vomiting and headache. These events were typically mild and transient in nature. In the placebo-controlled studies, the rates of occurrence of these events did not differ significantly from those of the placebo.

Romark Laboratories of Tampa, Fla., is the sponsor of the approved New Drug Application (NDA), Alinia for Oral Suspension. Alinia is designated as an orphan drug. Orphan drugs are developed to treat rare diseases, or conditions that affect fewer than 200,000 people in the U.S. The Orphan Drug Act provides a seven-year period of exclusive marketing to the first sponsor who obtains marketing approval for a designated orphan drug.

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available.

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