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Specializing in Gastrointestinal & Liver Disorders

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Dockets Management Branch
Food & Drug Administration
Department of Health & Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: DOCKET NUMBER: 00P-1499/CP1

Dear Dr. Henney:

I am a board certified gastroenterologist and internist practicing in Lansdale, Pennsylvania. It has been brought to my attention that the Food & Drug Administration is reviewing the efficacy and safety of Alosetron (Lotronex). From a personal perspective I have found this medication, when used in the appropriate setting, to be highly effective and well tolerated. In fact, many of my patients with diarrhea predominant irritable bowel syndrome who have not responded to prior standard therapy for irritable bowel syndrome have noted significant clinical improvement while taking Alosetron. Recently I attended the American College of Gastroenterology meetings in New York City where a symposium was held by the world's experts regarding irritable bowel syndrome. Data presented at that time, as well as discussions with many of my colleagues, reinforced the utility of this medication.

In summary, I have found Alosetron to be a valuable medication and I would hope the Food & Drug Administration would continue to allow the use of Alosetron for the treatment of diarrhea predominant irritable bowel syndrome.

Sincerely yours,

Donald L. Miller, M.D.

DLM:lap
Dictated, but not read.

cc: Carolyn Keba
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