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Board Certified in Gastroenterology
Practice Limited to Gastroenterology and Liver Disease

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November 16, 2000

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Jane Henney, M.D.
Commissioner, Food and Drug Administration
Docket No OOP-1499/CPI
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Dear Dr Henney,

As part of one of the largest Gastroenterology groups in the Baltimore, MD area, I am writing to you regarding the review of Lotronex that is taking place before the FDA. I feel this medication has tremendous benefits when prescribed for the appropriate patient and should remain part of our armamentarium when treating the very difficult irritable bowel syndrome patient. To date these patients are extremely difficult to satisfy and Lotronex is extremely helpful in treating these diarrhea predominant patients.

We respectfully request that the FDA continue to permit Lotronex as part of our prescribing regimen. We are aware of the constipation side effects and how to effectively treat it. My practice has many patients who have benefited from the medication and they will be extremely disappointed if this medication were no longer available. I would be happy to provide additional information regarding our use of Lotronex. Thank you for your consideration.

Sincerely,



Michael S. Siuta, M.D.

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