



# Hanover Medical Specialists, P.A.

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## CLINICAL RESEARCH

Kathy F. Miller, RN

## CHIEF EXECUTIVE OFFICER

Barbara Maisenhelder

November 21, 2000

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Jane Henney, MD  
Commissioner, Food and Drug Administration  
Dockets Management Branch  
Food and Drug Administration  
Dept. of Health and Human Services, Room 1-23  
12420 Parklawn Drive  
Rockville, Maryland 20857

Dear Dr. Henney,

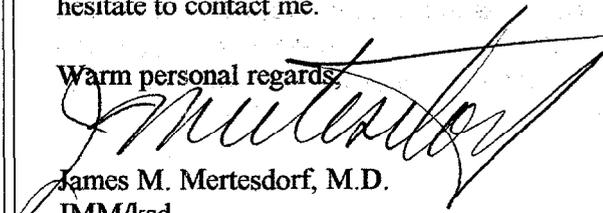
I am a Gastroenterologist in private practice in Wilmington, North Carolina. My practice is restricted to gastroenterology. A significant portion of my practice involves the diagnosis and care of irritable bowel patients.

I have prescribed Lotrinex since it became available for patient use. Like all medications it has specific indications and potential side effects. I found however that certain segments of my population which had severe diarrhea associated with irritable bowel that did not respond to other measures, some have responded dramatically to the use of Lotrinex. One woman in particular was unable to attend her son's pre-wedding planning in Texas because she was unable to get on an airplane for the flight from Wilmington to San Antonio, Texas. She was having on average 10 to 12 stools per day and had been worked up extensively. Within several weeks of beginning Lotrinex, her bowel movements decreased from 10 - 12 per day to 3 - 4 per day and were controllable. This allowed her to attend the pre-planning stages of her son's wedding in addition to the wedding. She otherwise would have had to miss these activities.

My use of Lotrinex is restricted to patients with diarrhea as a sole manifestation of irritable bowel and in addition they are counseled with respect to potential side effects of severe constipation, bloody diarrhea and abdominal pain. If they experience any blood per rectum, they are to call the office immediately and talk to myself or the physician on call. In addition, if they develop constipation, they are to cease taking the medication and to contact the office if they do not have a bowel movement for two days. If they do not respond to appropriate measures including use of laxatives, Lotrinex is discontinued and they are not rechallenged.

Following the above protocol for use of Lotrinex, my patients have not experienced any untoward side effects and many have benefitted. If you have any questions, please do not hesitate to contact me.

Warm personal regards,

  
James M. Mertesdorf, M.D.  
JMM/ksd

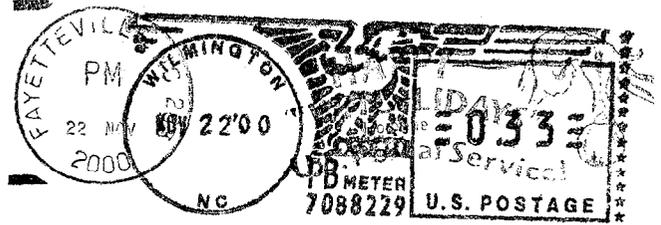
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ADDRESS SERVICE  
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