

June 18, 2001.

Ms. J. Woodcock,
Dockets Management Branch,
U.S. Food and Drug Administration,
5630 Fishers Lane, Room 1061,
HFA - 305,
Rockville, MD 20852

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Re: Plea for Approval of ZELMAC - Docket #OIP - 0259

Dear Ms. Woodcock:

Recently I was asked by Catherine Montgomery to write to you to plead on her daughter's behalf for your attention to this matter.

When we moved to Knoxville, TN four years ago, Heather Montgomery was the first girl my daughter, Megan, made friends with. I was very impressed by Heather's outgoing and energetic personality. When Megan and Heather played in our swimming pool the giggles were infectious. They were two young girls on the cusp of adolescence. Heather was healthy and had the usual adolescent's craving for junk food. Within one year I began to notice a change in Heather. Then, one day, she came to our house and I was shocked by her appearance. I remember asking my daughter if Heather had an eating disorder. Heather had gone from being a 'slightly chubby' pre-adolescent to appearing malnourished. What concerned me the most was not just how 'skinny' she was, but how frail she appeared. I knew there was something very wrong.

Heather is not the first person I have known who has suffered from Irritable Bowel Syndrome (IBS). A fellow student at university, some 20 years previous, had lost her colon to the condition.

I understand that Heather's IBS is constipation dominant, and that her condition may very well be treatable with medication. I know that she is unable to take a medication commonly prescribed for IBS sufferers because of her heart condition. Catherine has told me that ZELMAC or ZELNORM is the medication that might possibly provide Heather with some relief. Hopefully, this medication would keep her from surgery. This should always be the last step in a course of treatment.

I would like to impress upon you the effect that Heather's condition has had on her development. My own daughter has excelled at her studies, has rarely missed a day of school, and has been rewarded with acceptance at the Governor's School for the Arts this summer. Heather has had many difficult days. Her attendance has been irregular. I'm sure there are many days when she attended school when she should have been home resting. This irregular attendance has definitely had an effect on her performance in school. Heather's condition precluded her from even considering applying to the Governor's School, although she is a very talented artist. Acceptance at the School will undoubtedly lead to scholarships. This chance has been lost to Heather.

It is easy to say that she's young and has time to overcome the obstacle set in her path. Ask yourself this. Would you want your child's future impeded by a condition that could be controlled by medication? I think not. Heather is far too intelligent and talented a young woman to be debilitated by IBS, and prevented from achieving her full potential.

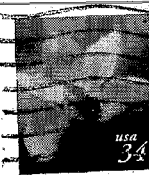
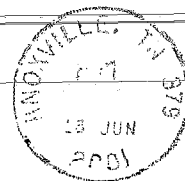
I understand there are 30 million IBS sufferers in the United States. Those numbers alone should be sufficient to hasten the introduction of ZELMAC to the U.S. market.

Sincerely, Celeste Walker.

Celeste Walker
OIP-0259

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