(1.) Docket #
01P-0169

To whom this may concern:
I am writing to you to express how disappointed I was in your agency, regarding the recent decision involving Zelnorm.

I have suffered with constipation predominant Irritable Bowel Syndrome for the last Twenty years.

Over the years I have taken many medications both prescription and over-the-counter to relieve the symptoms of this syndrome. Mostly, I have discontinued using these products because they either did not work or I could not tolerate the side effects.

I am currently taking Magnesium Hydroxide on a Daily Basis as well as Ascorbic acid and a fiber supplement.

While the combination of medication

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supplements helps to alleviate some of the symptoms, it does not, however, bring about a complete resolution of all symptoms.

There are warnings about the potential dangers of combining Magnesium Hydroxide with other medications. Additionally, I am also aware that Magnesium Hydroxide is an agent primarily designed for occasional use only. Clearly, this is not a good long-term solution.

However, due to the severity of my symptoms and the complete lack of any other medications designed to treat this specific symptom pattern, I feel I have no other choice but to take my chances and continue this medication.

My understanding of is that with this decision it may take

up to an additional two years to complete the approval process. In my opinion this is unacceptable. Two years is too long, for an individual suffering with this syndrome to wait for this medication.

And while there are no guarantees that this drug will work for every one who takes it, there are many people who will benefit from the approval of this drug.

The approval of this drug, quite literally can mean the difference between a good quality of life and a poor quality of life.

Don't let what happened with Lotronex cloud your judgement concerning Zelnorm.

(4)

Please reconsider your decision regarding the Zelnorm application by Novartis.

Thank you for your consideration.

Sincerely,

M. M. Polito

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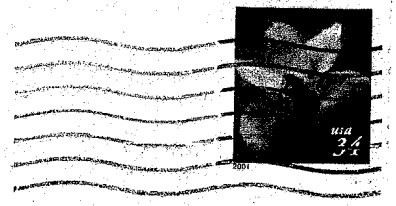

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