

May 8, 2003

Kimberly Littleton Topper  
Center for Drug Evaluation & Research HFD-21  
Food and Drug Administration  
5630 Fishers Lane Room 1093  
Rockville, MD 20857

Re: **Xolair** - by Genentech

Dear Ms. Topper:

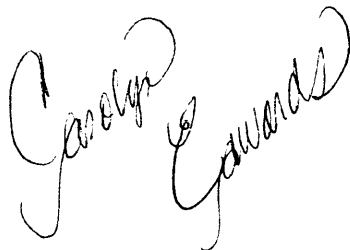
Forgive the delay in sending this letter, I have been traveling outside of the country. I know you have many letters to read, so I will make mine brief.

I was in the clinical trials for Xolair January 2002-January 2003. Ten years ago I ended up in the emergency room and was hospitalized for 5 days. At that time I was diagnosed with severe asthma. From that time on I have been under the excellent care of medical specialists. Even with that, over the last 10 years I have taken 19 different medications both inhaled and ingested to try to control my asthma symptoms. Staying on top of asthma symptoms is rather like spinning a dozen plates on sticks and trying not to drop any of them. An asthma patient can become very ill, very quickly. In these 10 years the only medication that really kept the symptoms in check were steroids. So basically, *I was steroid dependent*. I could not be off steroids more than two weeks before the symptoms would return.

January 2002, I began Xolair. I received 2 injects every other week for one year. I had to be off steroids to participate in the clinical trials, so I was understandably nervous when we began the trials. After the 2<sup>nd</sup> set of injections, the 2<sup>nd</sup> week of the clinical trials I felt excellent. It was like having a new life. In the year of the clinical trials *I have had no need for steroids*. I have and *no side effects* from Xolair. I have been off of the Xolair for five months and I am still steroid free. *This is an awesome drug*. I encourage you to approve this drug. It will not only save lives, but also improve lives. Lives like mine.

All of the drugs now on the market are used to "treat the symptoms" of asthma. *Xolair prevents the symptoms.*

Carolyn Edwards  
5458 El Carro Lane  
Carpinteria, CA 93013  
805-684-2551

A handwritten signature in cursive script that reads "Carolyn Edwards". The signature is written in black ink and is positioned to the right of the typed name and address.