

1769 Clark Hills Circle
Johns Island, SC 29455

April 16, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA (Docket No. 99N-0386) Talking With Stakeholders about FDA
Modernization

Dear Sir or Madam:

I plan to attend the April 28, 1999 CVM Stakeholders Meeting at the Johnson County
Community College, Overland Park, Kansas.

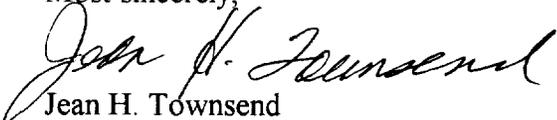
With reference to that meeting I am writing as a consumer, and one with personal knowledge of
how lack of consumer information can lead to disaster. In particular I am writing about animal
health products, for it is my belief that animal medications should be prescribed with adequate
warnings just as human medications are prescribed.

In particular I am concerned about the drug Rimadyl, introduced by Pfizer in January 1997.
When I asked for it for my senior Chocolate lab, it was prescribed with no instructions as to what
possible adverse side effects may occur. My lesson was learned the hard way. My dog within 30
days of being on the drug (though it appeared to help him at first) suddenly collapsed and later
had to be euthanized. I was and still am devastated. It was a shock of major proportions - never
did I think a drug so widely advertised as a "miracle" drug could cause such reaction in an animal.

It is my greatest hope that the FDA will institute stricter regulations that will make sure all
medications, both human and animal, are dispensed with adequate warnings - and that they
warnings will be clearly understood by lay persons such as myself.

I am enclosing for your information a copy of a letter I wrote to Dr. Edward W. Kanara, DVM,
of Pfizer Inc. in response to his telephone call to me last August.

Most sincerely,



Jean H. Townsend

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(843) 958-4290 (Office Telephone)
(413) 771-3070 (E-Fax No.)

99N-0386

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P. O. Box 232
Johns Island, SC 29457

September 26, 1998

Edward W. Kanara, DVM., DABVP
Director Technical Services
Companion Animal Division
Pfizer Inc.
812 Springdale Drive
Exton, PA 19341-3803

Dear Dr. Kanara:

This letter is in reply to the telephone call from Dr. Jenkins and you on Tuesday, August 18, 1998, and your follow-up letter dated September 2, 1998. You and Dr. Jenkins telephoned to attempt to clear up some of my concerns regarding the role Rimadyl played in the death of my Chocolate Lab, George. Perhaps "complete devastation" would be a better way to describe my feelings. My George is gone so now I am concentrating on sharing my experience with other Rimadyl users to help avoid further deaths and illnesses. Public Awareness, I believe, is what it is all about.

During the August 18 telecon you stated: "Our major concern is to ask for assistance if you have any information on any cases that have not been reported to Pfizer. We do feel that we would like to do whatever we can to report those as required by the FDA." Your September 2, 1998, letter requests that I "share with Pfizer any information on the 60 dogs you have referred to in separate correspondence as potentially having had adverse reactions to Rimadyl." Sadly that figure has grown, and I find it increasingly difficult to monitor this situation.

As I am sure you are aware, immediately after George's death, I began searching the Internet for others who had similar experiences with treating their dog with Rimadyl. This search has been a virtual roller coaster ride for me with ups (when my information may have saved a dog's life) and downs (when it was too late). I have developed a true camaraderie with many other people whose lives have been changed by Rimadyl. With this camaraderie comes a mutual respect for privacy and confidentiality. Therefore, I will not provide Pfizer with "any information on any cases" that I have personally documented. The information you are requesting from me must come directly from the individual. It should be fairly easy for Pfizer to contact these people. As Pfizer is no doubt aware, the Senior Dogs Web Site (www.srdogs.com) has been doing a tremendous service in providing information to the general (worldwide) public on Rimadyl. Many cases are posted on this site as well as on other sites such as the AcmePet Dog Health bulletin board (www.acmepet.com), AOL Pet Care Forum and in the various dog newsgroups. A public announcement posted by Pfizer on these sites requesting contact with Rimadyl users who

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experienced an adverse reaction will get Pfizer the information you're looking for. Pfizer can also 'reach out' and contact many of these people personally via email. As for my part, I will personally see to it that Pfizer's public statement reaches those cases that I am aware of.

Myself and many others are truly disappointed Pfizer has not taken a more aggressive role in making more public and further educating vets and dog owners of Rimadyl's possible adverse reactions - reactions that have literally devastated the lives of many dog owners. A change in the package insert is not enough. I will never get over how my dog, with his eyes, begged me to end his misery! That look will haunt me until the day I die. And to that end enclosed you will find some of the real life, first-hand experiences of what has been called "Rimadyl Roulette."

Sincerely,



Jean H. Townsend

encls.

cc: Mr. William Steere, Chairman of the Board,
Pfizer, Inc.
Dr. Christine Jenkins, Pfizer Animal Health
Dr. Michael Vanschoyck, Pfizer Animal Health
Honorable Mark Sanford
Honorable Strom Thurmond
Honorable Ernest F. Hollings
Dr. Neal Bataller, FDA CVM

