



November 29, 2005

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

Re: Docket No. 2005D-0385, Draft Guidance for Industry **"Using Electronic Means to Distribute Certain Product Information"** (70 Federal Register 57300-57301; September 30, 2005)

Health is our top priority at Pfizer, so we support any initiatives that improve the best use of our medicines. Indeed, Pfizer would like to acknowledge FDA's efforts in preparing the Draft Guidance.

We support using electronic means to communicate product information; however, we would like the Agency to consider these two (2) recommendations:

1. We suggest that FDA develop a method to ensure that communication and instructions to the public are followed. This should include metrics and a pilot period to assess the effectiveness of electronic communication as described in the Draft Guidance, but under conditions of actual use (Ref. lines 222-223).
2. We suggest that the sentence in lines 24-25 be modified to read: "*We recommend the use of electronic communications as an alternative or parallel system for conveying all important product safety information,*" as consideration is suggested for the targeted audience. Since not all of the general public may have ready access to electronic means there should be an emphasis throughout this guidance that electronic means is an alternative or a parallel mode of communication in addition to standard existing means.

Pfizer appreciates the opportunity to provide the above comments to further clarify and strengthen the Draft Guidance. We would be pleased to respond to any questions the Agency may have about our comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Maria Guazzaroni Jacobs".

Maria Guazzaroni Jacobs, Ph.D.
Director/Team Leader
Regulatory Monitoring
Global Quality Operations
Pfizer Inc.