

Scott M. Lassman
Assistant General Counsel



June 23, 2003

Ms. Mary Gross
Office of Drug Safety (HFD-400)
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857

Re: Docket Number 02N-0201; Minimizing Medication Errors – Methods
for Evaluating Proprietary Names for Their Confusion Potential;
Public Meeting

Dear Ms. Gross:

The Pharmaceutical Research and Manufacturers of America (PhRMA) requests an extension of the comment period for written comments on the issue of similarity in drug naming, including the questions posed by the Food and Drug Administration (FDA) on the meeting announcement website. Full public input on these issues will be critical to the FDA as the Agency moves forward with developing a draft guidance on this topic. PhRMA is pleased to have the opportunity to sponsor this meeting with FDA and hopes that the oral presentations of our company experts will be of use to FDA as it moves forward on this matter.

PhRMA believes that the technical and legal issues that will be discussed at the June 26 Public Meeting require more time to respond to than the FDA has allotted in the published Federal Register notice of May 30, 2003. In that notice, FDA announced that written comments would be accepted by July 15, 2003. This deadline falls only nineteen (19) days after the Public Meeting, much less than the 60 to 90 days that FDA routinely allows for comments on regulatory documents. Moreover, the Fourth of July holiday falls squarely within this 19 day period, further limiting the time to prepare comments. PhRMA does not believe this provides sufficient time for industry to incorporate the comments and learning from the Public Meeting into its written comments to FDA. FDA will be ill-served if the Agency does not receive detailed comments on all of the critical issues raised not only by the list of questions provided by FDA but also during the Public Meeting. To this end, PhRMA requests a 30 day extension of the comment period so that we can best inform the Agency on these issues.

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I look forward to the Agency's prompt response on this matter given that the deadline for written comments is fast approaching.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott M. Lassman", with a long, sweeping horizontal line extending to the right.

Scott M. Lassman

cc: Dockets Management Branch (HFA-305)