Alan Goldhammer, PhD
Associate Vice President,
US Regulatory Affairs

PhRMA

July 11, 2003

Dr. Randy Levin
Center for Drug Evaluation and Research
(HFD-001)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dr. Michael Fauntleroy
Center for Biologics Evaluation and Research
(HFM-588)
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852

Re: Request for an extension of the comment period for Docket Number 2003D-0231; Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Postmarketing Periodic Adverse Drug Experience Reports; 68 Federal Register 37504; June 24, 2003

Dear Drs. Levin and Fauntleroy:

The Pharmaceutical Research and Manufacturers of America (PhRMA) requests an extension of the comment period for the above noted draft guidance. PhRMA believes that this draft guidance raises a number of key issues that requires more time than the Agency has allotted. As you are aware PhRMA, through our Electronic Regulatory Submissions Task Force has been working with FDA to establish a number of standards for the submission of a variety of regulatory documents. This particular guidance is complicated by the recent publication of a proposed rule that will markedly alter the safety reporting requirements for human drug and biological products. Many of the same PhRMA company experts who will assist in preparing comments on the draft guidance are also working on the proposed rule. While the proposed rule will take some time to finalize, it poses significant implications for this draft guidance.

PhRMA believes that FDA will be better served by a robust set of comments on the draft guidance. To this end, PhRMA requests a 60 day extension of the comment period for the draft guidance on electronic adverse drug experience reports.

I look forward to the Agency's prompt response on this matter,

Sincerely,

cc: Ms. Jane Axelrad