

**Rosemary Cook, MBA**  
Assistant Vice President  
U.S. Regulatory Affairs



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July 22, 2005

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

Re: Docket No. 2005D-0169; Draft Guidance on Useful Written Consumer Medication Information; 70 Federal Register 30467; May 26, 2005.

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) welcomes the opportunity to comment on the above referenced draft guidance issued by the Food and Drug Administration (FDA). PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members invested an estimated \$38.8 billion in 2004 in discovering and developing new medicines. PhRMA companies are leading the way in the search for new cures.

PhRMA is a strong believer in empowering patients by providing information regarding their prescription drugs. Useful information improves patient compliance, helps patients to avoid preventable errors, and results in superior health outcomes. It is in the best interests of healthcare providers and pharmaceutical manufacturers to ensure that patients are educated about the drugs prescribed to them. Therefore, PhRMA supports FDA's efforts to issue the guidance, *Useful Written Consumer Medication Information* (CMI), and agrees that the factors discussed in the guidance will assist third parties (e.g. pharmacies, private vendors, healthcare associations) to develop useful written CMI. PhRMA agrees that the most recent FDA-approved professional labeling or package insert (PI) serves as the source document for the information contained in CMI. The draft Guidance clarifies how the *Action Plan for the Provision of Useful Prescription Medicine Information* (the Action Plan) should be interpreted and implemented to meet the usefulness criteria provided in the Plan. The Guidance adequately outlines the FDA's expectations of CMI content for all interested parties, and is responsive to requests made of the FDA at the July 31, 2003 meeting with CMI stakeholders.

**2005D-0169**

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*Pharmaceutical Research and Manufacturers of America*

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In closing, PhRMA reiterates its support of FDA's efforts to provide guidance regarding the criteria for useful consumer medication information specified in the Action Plan.

We thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Rosemary Cook". The signature is written in black ink and is positioned below the word "Sincerely,".