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DEPUTY GENERAL COUNSEL



June 11, 2002

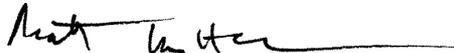
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: *FDA 'Request for Comments on First Amendment Issues'*  
Docket No. 02N-0209, 67 Federal Register 34942, May 16, 2002  
**Request For 60-Day Extension Of Public Comment Periods**

The above-referenced request for public comments on a range of First Amendment issues is of considerable interest to the Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies, and we look forward to providing comments. However, PhRMA believes an extension of the comment period is warranted, because the range of issues outlined in the notice is extensive, and the First Amendment aspects are complex and challenging, as evidenced by the nine specific questions listed for comment.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. The industry, which invested more than \$30 billion in 2001 in discovering and developing new medicines, is leading the way in the search for new cures. Although PhRMA began the consideration and preparation of comments coincident with publication of the Federal Register notice, we are convinced that the July 30 deadline for comments, and September deadline for responsive comments, will prove inadequate. Accordingly, PhRMA requests that FDA publish notice of a 60-day extension of these comment periods, to September 30 (for submission of initial comments in response to this notice), and November 12 (for submission of responses to initial public comments). We suspect other interested stakeholders would also appreciate such a 60-day extension of this important comment period.

Sincerely,

  
Matthew Van Hook

cc: Catherine Lorraine, FDA Office of Policy, Planning, and Legislation (HF-11)

02N-0209

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*Pharmaceutical Research and Manufacturers of America*