

# BARNES & THORNBURG LLP

<http://www.btlaw.com>

750 17<sup>th</sup> Street N.W.  
Suite 900  
Washington, DC 20006-4607

Switchboard: (202) 289-1313  
Fax: (202) 289-1330

Walt A. Sanders  
Co-chair, Federal Relations Group  
Direct Dial: (202) 371-6345  
E-mail: [walt.sanders@btlaw.com](mailto:walt.sanders@btlaw.com)

September 22, 2005

Docket No. 1976N- 0052G  
Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: Request for Extension of Time for Submitting Comments

Dear Docket Management Group:

Our firm represents the American Council on Regulatory Compliance (ACRC), a group of small businesses that manufacture, distribute and retail cold remedies and other products made with ephedrine and pseudoephedrine.

The proposed rule, which would have a substantial and devastating impact of the members of the ACRC, requires formal comments to be submitted by November 10, 2005. This date will present a substantial hardship for the ACRC because the members of the ACRC are small companies with limited resources and even more limited time to respond. Many of these companies have customers in Mississippi, Florida, and Texas adversely affected by the recent hurricane-related national disasters. They also have been responding to international business emergencies and coping with legislative initiatives and legal issues initiated by the Federal government. All of these issues are having a substantial impact on their businesses.

Given the fact that the Food and Drug Administration has been developing data in support of this proposed rule over the past 10 years, the ACRC believes it will be placed at a substantial economic and procedural disadvantage without additional time to formulate its comments.

Therefore, the ACRC hereby requests an extension of at least an additional 180 days (April 20, 2006) to submit its comments on the proposed rule contained in Docket No. 1976N-0052G.

Please respond to this letter as soon as possible to enable our clients to prepare an appropriate response.

Sincerely,



Walt A. Sanders