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

## Supplemental Information to Request for Extension of Time for Submitting Comments

Dear Docket Management Group:

FDA has requested the American Council on Regulatory Compliance (ACRC) to provide supplementary information to its September 22, 2005 request for a 6-month time extension of the November 10, 2005 deadline for the proposed rule to ban combination ephedrine products.

Our September 22, extension request, indicates that the current deadline presents 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. Officials at FDA contend that the proposed rule will have a "minimal impact" on companies that produce and consumers who use combination ephedrine products. To the contrary, the ACRC believes the proposed rule would have a substantial impact on small business and consumers.

The ACRC consists of 9 primary producers/distributors of private label combination ephedrine products. These companies, alone, have estimated annual wholesale sales of over \$50 million in combination ephedrine products. Retail sales of these products would yield substantially higher figures -- possibly over one hundred million dollars. In addition, there are over 500 smaller distributors, who are not ACRC members, who conduct business in every state, including those states substantially affected by recent hurricanes. A state-by-state list is attached. The ACRC, and other small distributors, sell private label combination ephedrine products to thousands of retail stores in virtually every state in the Nation.

FDA is sorely mistaken if it believes the impact of banning combination ephedrine products is minimal. Banning combination ephedrine products will have a substantial impact on thousands of small businesses and millions of consumers throughout the nation.

An extension of time is absolutely essential.

Please contact Walt Sanders at (202)371-6345 if you require further information.

Sincerely,



Walt A. Sanders

Enclosure

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