



*Producers of Quality  
Nonprescription Medicines and  
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## **CONSUMER HEALTHCARE PRODUCTS ASSOCIATION**

*Formerly Nonprescription Drug Manufacturers Association*

August 30, 2000

Steve Solomon  
Office of Regional Operations  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Steve:

On behalf of the Industry Coalition on 21 CFR Part 11, thank you for the opportunity to meet with you and other members of the FDA Part 11 Compliance Committee on September 13, 2000. We hope that the meeting will be the first in a continuing dialogue and series of constructive next steps to address the issues, concerns and solutions surrounding Part 11, particularly its interpretation and implementation.

The Coalition is approaching this meeting with a strong spirit of cooperation. We believe that the regulators and the regulated industries share a common goal -- to provide consistently high quality products to the public -- and if we can share our combined expertise and experience, we will benefit all parties.

To help the FDA attendees prepare for the meeting, I am sending you the attached short paper describing the Coalition's concerns, along with a number of constructive recommendations, which we would like to discuss at the September 13 meeting. While we have suggestions for approaches to most of the areas of concern, there are others where the solution is not obvious (e.g. long-term archiving). We believe it will be important to establish workable guidances in a variety of areas that will benefit both industry and the FDA as both parties move towards full compliance with Part 11. We are most interested in FDA's view of the attached paper and the points we have raised.

Thank you again. We look forward to meeting with you and your colleagues on September 13.

Sincerely,

William W. Bradley  
CHPA Vice President - Technical Affairs  
Chairman, Steering Committee  
Industry Coalition on 21 CFR Part 11

WB/mm