



MAR 15 2005

Alan Goldhammer
Chair, Industry Coalition on Part 11 &
Associate Vice President for Regulatory Affairs
Pharmaceutical Research and Manufacturers of America
1100 15th Street, NW
Washington, DC 20005

Frederick Razzaghi
Director of Technical Affairs
Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006

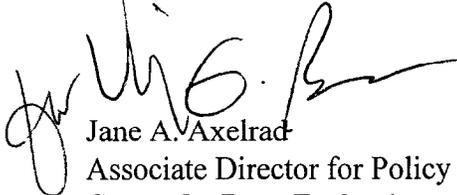
Re: Docket No. 2004P-0429/CP1

Dear Mr. Goldhammer and Mr. Razzaghi:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated September 17, 2004, requesting that FDA revoke 21 CFR part 11 because the provisions are largely superseded by the Government Paperwork Elimination Act.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,



Jane A. Axelrad

Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0429

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