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2 July 2003 via e-mail and First Class mail

Mr. Joseph Famulare
Director of DMPQ
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Building MM2, Room RM438
Mailstop HFD-320
Rockville MD 20852

Re: Follow up to SQA letter dated 8 May 2003 re Draft Guidance on Scope and Application of 21 CFR 11

Dear Mr. Famulare:

On behalf of the Computer Validation Initiatives Committee of the Society of Quality Assurance (CVIC), I would like to thank you for your original willingness to meet with us to discuss our concerns with the draft guidance on the Scope and Applicability of Part 11, but also to express our disappointment for the cancellation of that meeting.

Our concern is magnified by the fact that it does not appear that the docket has been kept up to date with the comments submitted during the comment period. Many of our members have submitted comments that are not yet viewable on the docket, and we feel that the comments that are available do not represent an accurate cross-section of the industry. Our goal for the meeting was to assure that you were cognizant of the spectrum of opinions and that you heard first hand of the issues that are already arising over the proposed Scope and Application changes that would be finalized while Part 11 is being further evaluated.

The SQA is an organization of quality assurance professionals. Like FDA, our members have the roles of being the "overseers" in their organizations, the objective reviewers to assure consumer safety, product quality and data integrity. We in CVIC specialize in assuring consumer safety, product quality, and data integrity when those goals are managed via computer systems. We are the people who have interpreted and implemented Part 11 in our workplaces. We have lived with the claims that Part 11 stifles innovation and reduces business profitability. What we have seen is the opposite. Part 11 has forced industry to adopt quality standards that have improved the way the regulated IT organizations manage their applications, systems, and infrastructures. It has made computer system vendors become more accountable for their development and support practices. It has improved the reliability, repeatability, and integrity of the data going to FDA for safety reviews. Because of the inherent common sense of Part 11, other organizations and disciplines look to it for guidance in establishing good computer system practices. It is our professional opinion that any reduction in the scope and applicability of

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Part 11 will result in a decline in the reliability and integrity of the data going to FDA and may result in poor decisions, both by industry and FDA, that are based on faulty, unrepeatable or unverifiable data. In our opinion, the wording in the guidance document does not clarify Part 11, but only confuses.

In hindsight, we would have been happy to have an initial opportunity for a dialog prior to the drafting of the guidance. Unfortunately, our perception is that the drafting and commenting period for this guidance did not fulfill the spirit of equal access that we have observed in other regulations and guidance documents.

SQA and CVIC have always encouraged good relationships with members of the regulatory agencies and it is our hope that we can establish a good relationship with you and your colleagues. To that end, we would like to know your interest in being invited to speak about the guidance document at either our Annual Meeting (October 12-16, 2003 at the Crystal Gateway Marriott in DC) or more informally at our quarterly CVIC meeting, held in Baltimore on July 14-15, 2003. Please let us know if you are interested in either of these meetings. We look forward to working with you in the future.

Sincerely,

Patricia M. Miller

Patricia M. Miller
Chair, SQA Computer Validation Initiatives Committee