medrad®

April 29, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket Numbers 03D-0060, 99D-1458, 00D-1538, 00D-1543,OOD-I542, and OOD-1539. Draft Guidance for industry on "Part 11, Electronic Records, Electronic Signatures-Scope and Application"

Medrad, Inc.
One Medrad Drive
Indianola, PA 15051-0780
(412) 767-2400

Dear Sir/Madam,

First, let me take the time to thank you for the opportunity to comment on your insightful changes to 21 CFR, "Part 11,Electronic Records, Electronic Signatures. After careful review of the draft guidance, we found that there are still some concepts that need clarification. Below are Medrad's comments for your consideration.

1. With regard to Section III DISCUSSION, Letter C. Approach to Specific Part 11 Requirements, 3. Legacy Systems: What specifically is meant with the enforcement discretion and risk-based approach to PART 11 regarding systems that were operational before August 20, 1997?

2. Under Section III DISCUSSION, Letter C. Approach to Specific Part 11 Requirements, 3. Legacy Systems, it implies that systems in use before August of 1997 do not have to be remediated. Is this a true statement or does it only apply to systems that have not had upgrades or data changes?

3. The Guidance titled " 21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps" was very well written and was accepted by industry as a useful tool. Will this be incorporated into the re-write of Part 11 or is there a possibility of it being re-released?

4. In Section III, Letter C. Approach to Specific Part 11 Requirements, 2. Audit Trail, The currently released Guidance states, "Audit trails are particularly important where the users are expected to create, modify, or delete regulated records during normal operation." and "Even if there are no predicate rule requirements to document, for

99D-1458 C20

example, date, time, or sequence of events in a particular instance, it may nonetheless be important to have audit trails or other physical, logical, or procedural security measures to ensure the trustworthiness and reliability of the records." So basically you are saying in most cases, you need to have audit trails but they do not necessarily need to be computer generated?

5. Repeatedly, throughout the current guidance there are references to "predicate rule requirements", and in Section III DISCUSSION, Letter A. Overall Approach to Part 11 Requirements you mention, "For those records that we are now clarifying are subject to Part 11, we intend to exercise enforcement discretion with regard to Part 11 requirements for validation, audit trails, record retention, and record copying, in the manner described in this guidance, and in applying Part 11 to systems that were operational before the effective date of Part 11." Could the FDA provide a reference list of the required quality records associated with the predicate rules for industry to use as an aid in achieving compliance?

In general, we have found the changes released with the Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application to be a welcomed improvement for all parties governed by Part 11. Additionally, we find that these changes more closely map to the Agency's shift to more "risk-based" enforcement of all good manufacturing practices. With the inclusion of these additional clarifications, the final guidance will prove to be a very useful tool to all FDA-regulated companies.

We here at Medrad, inc. appreciate the opportunity to comment on this guidance. Please feel free to contact me at (412) 767-2400 x3411 if you have any questions regarding this letter.

Sincerely,

William R. Fisher
Senior Quality Assurance Software Engineer
(412) 767-2400 (X3411)
wfisher@medrad.com